Submitter : **Mr. R. Alan Burns** **Date: 09/12/2005**

Organization : **Society for Radiation Oncology Administrators**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See attachment for comment from the Society for Radiation Oncology Administrators
Re: Proton Beam Therapy Payment Classification

CMS-1501-P-345-Attach-1.DOC

Submitter : Mr. Gregory Ripley **Date:** 09/12/2005

Organization : McKenzie Willamette Medical Center

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Regarding the proposed Outpatient Prospective Payment System (OPPS) rates for 2006:

A June 30, 2005, report on hospital outpatient department pharmacy handling costs prepared by the Medicare Payment Advisory Commission (MedPAC) noted that these expenses were "not insignificant" and that they "made up 26 percent to 28 percent of pharmacy departments' direct costs." Instead of accepting MedPAC's analysis, CMS proposes to pay only an additional 2 percent of the ASP scaled for budget neutrality to cover the handling costs of these drugs."

This reimbursement formula is inadequate to cover handling costs of drugs. We may be forced to limit or eliminate the treatment of patients in outpatient settings. The ramifications of instituting this formula will be disastrous. The places and processes of providing services will change - to the detriment of patients who will not receive treatment by their providers of choice. Inadequate reimbursement to hospital outpatient departments will impact the quality, safety and level of their services.

I support the proposal being made by the Association of Community Cancer Centers (ACCC) that CMS consider an allowance of 8% to cover pharmacy handling and overhead expenses for all drugs reimbursed under the hospital OPPS, in addition to ASP + 6% to cover the drug acquisition cost.

CMS should collect hospital charge data for overhead costs for two years to determine if even the 8% rate is adequate and consider new reimbursement rates for these costs for payment in 2008.

Submitter : Mr. Mark Baker **Date:** 09/13/2005

Organization : Private Citizen

Category : Device Industry

Issue Areas/Comments

GENERAL

GENERAL

Please corret the error in funding for Apligraf. Many people bennitfit from the great product. It is a cost effective wayt to treat chronic ulcers

Submitter : Mr. Bruce Baker **Date:** 09/13/2005

Organization : Priviate Citizen

Category : Device Industry

Issue Areas/Comments

GENERAL

GENERAL

Please correct the error in coding used for Apligraf. Apligraf has helped over 100,000 patients in the last 7 years.

Submitter : **Ms. Sarah Wells** **Date: 09/13/2005**

Organization : **Boston Scientific Corporation**

Category : **Device Industry**

Issue Areas/Comments

GENERAL

GENERAL

See Two Attachments (Comments and Appendix)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

Submitter : Ms. Sarah Wells **Date:** 09/13/2005

Organization : Boston Scientific Corporation

Category : Device Industry

Issue Areas/Comments

GENERAL

GENERAL

See 2 Attachments

CMS-1501-P-350-Attach-1.PDF

CMS-1501-P-350-Attach-2.PDF

Boston Scientific

Randel E. Richner
Vice President
Government Affairs and
Reimbursement & Outcomes
Planning

1331 Pennsylvania Avenue, NW
Suite 550 South
Washington, DC 20004

BY ELECTRONIC SUBMISSION

September 12, 2005

The Honorable Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates (CMS-1501-P)

Dear Administrator McClellan:

Boston Scientific Corporation (Boston Scientific) and Advanced Bionics Corporation (a Boston Scientific company) welcome the opportunity to comment on the Centers for Medicare and Medicaid Services's (CMS's) Proposed Changes to the Hospital Outpatient Prospective Payment System (OPPS) and Calendar Year (CY) 2006 Payment Rates (CMS-1501-P, Federal Register, Vol. 70 , No. 141, July 25, 2005).

As the world's largest company dedicated to the development, manufacturing, and marketing of less-invasive therapies, Boston Scientific supplies medical devices and technologies used by the following medical specialty areas, many of which provide beneficiary care in the hospital outpatient department setting:

- Electrophysiology;
- Endoscopy;
- Gastroenterology;
- Gynecology;
- Interventional Cardiology;
- Neuromodulation;
- Neurovascular;
- Oncology;
- Peripheral Interventions;
- Urology; and
- Vascular Surgery.

We are writing to comment on CMS proposals in the CY2006 OPPS Proposed Rule that have important implications for hospitals and their continued ability to offer Medicare beneficiaries the latest advances in outpatient clinical care. Attached to this letter please find our detailed comments (**Attachment A**), which address multiple topics pertaining to proposed payment changes for devices including device-dependent APCs, APCs of particular interest to Boston Scientific and policies related to new technology APCs and pass-through device categories. Below is a top-line summary of key issues and policy recommendations with page references to our attached detailed comments.

Device-Dependent APC Concerns (Section I – pages 1-5)
Boston Scientific remains supportive of packaging device costs to calculate payment rates under the prospective payment system for hospital outpatient services. However, we are very concerned about the continued inaccurate reflection of device-related costs in the claims data upon which APC payment rates are based. Hospitals' inconsistent billing practices and underreporting of c-codes, charge compression, CMS's inconsistent use of external data and heavy reliance on "single procedure" and "pseudo single" claims all compromise CMS's ability to set valid payment rates that do not fluctuate widely from year to year. CY2006 rate-setting based on CY2004 claims (where c-code reporting for devices was optional) poses a unique set of challenges for accurate accounting of device-related procedural costs during this rulemaking cycle.

While we appreciate that CMS conducted a detailed analysis to examine policy options for mitigating significant rate cuts facing device-dependent APCs for CY2006, we have serious concerns about CMS adjusting cost medians downward for 10 device-dependent APCs to 85% of respective cost medians for CY2005. We believe the magnitude of this reduction is too steep. Thus, for CY2006, we urge CMS to implement the recommended APC-specific adjustments described in our detailed comments (and summarized below), or alternatively, to set rates for these APCs at no less than 100% of CY2005 payment rates plus inflation and other update factors applied to all APCs. Beyond CY2006, we urge CMS to implement alternative rate-setting methodologies that more accurately and adequately reflect the costs associated with these and other device-related procedures that would be not be addressed by CMS's proposed policies.

Of particular concern to us are the median cost adjustments proposed for four device-dependent APCs – ***Implantation of Neurological Device*** **(APC 0222); Level VI** ***Ear, Nose and Throat Procedures*** **(APC 0259),** ***GI Procedures with Stents*** **(APC 0384);** and ***Cardiac Electrophysiologic Recording/Mapping*** **(APC 0087).**

For APCs 0222, 0259, and 0384, we recommend CMS make the following APC-specific adjustments:

- APC 0222 and APC 0259: We urge CMS to accept and utilize external data in recalculating the relative weights for these two APCs.

- APC 0384: We urge CMS to recalculate relative weights using only those claims where a c-code was reported as recommended by the APC Panel on August 18, 2005. We disagree with the APC Panel's proposal and rationale to reassign *Endoscopic Retrograde Cholangiaopancreatography (ERCP)* procedures from APC 0384 to a newly created APC

just for these procedures, and recommend that CMS maintain the current configuration for APC 0384 for CY2006. In the event that CMS decides to create a new APC for ERCP, we recommend that only those claims where c-codes were reported be used for calculating the median cost to set the new APC rate.

If the APC-specific adjustments cannot be implemented in the final rule using the alternative methodologies recommended above, we request that CY2006 rates for these specific APCs be set at no less than 100% of CY 2005 rates plus inflation and other update factors applied to all APCs.

For APC 0087, we also request that CMS set the CY2005 payment rate at no less than 100% of CY2005 rates plus inflation and other update factors applied to all APCs. Given the unique problems with capturing device-related costs in the CY2004 claims data for this particular APC, we believe the floor presents the most feasible short-term approach to ameliorate payment reductions that if unaddressed could jeopardize beneficiary access to outpatient care.

APC-Specific Issues (Section II – pages 5-16)
For CY2006, APC-specific issues of particular interest/concern to Boston Scientific include:

A. Reassignment of Laminectomy for Implantation of Neurostimulator Electrodes (CPT® 63655) from APC 0225 to APC 0040

We urge CMS to adopt the unanimous recommendation made by the APC Advisory Panel on August 18, 2005 to restructure *neurostimulation electrode implantation APCs* by creating three distinct APC groups to describe percutaneous implantation; laminectomy or incision for implantation; and cranial electrode implantation. This reassignment would mitigate an unwarranted and precipitous 73% drop in payment for CPT code 63655.

B. Designation of Non-coronary Intravascular Ultrasound (CPT 37250/APC 0416/C1753) as "Device-Dependent" and Methodology for Allocating Device-related Costs

We urge CMS to designate *non-coronary (peripheral) intravascular ultrasound (IVUS)* procedures (CPT 37250/APC 0416/C1753) as "device-dependent," a request we have formally made to CMS for the past several years and that was endorsed by the APC Panel on August 18, 2005. This modest but critical policy change will facilitate improved data capture of device-related costs in OPPS claims data by making hospital c-code reporting of this procedure mandatory. We ask CMS to continue to monitor the resource use of CPT 37250 relative to other procedures assigned to APC 0416 to determine whether potential reassignment is warranted for CY2007. Further, we ask CMS to adopt an alternative methodology for selecting claims and allocating costs associated with separately payable adjunctive hospital procedures, such as non-coronary IVUS, that are reported as "add-on" HCPCS codes. Boston Scientific offers a proposed solution in our detailed comments that involves splitting multiple procedure claims into "pseudo single" procedure claims that would reflect device costs specific to the relevant APC to which the single procedure is assigned.

C. Reassignment of Ureteroscopic Lithotripsy (CPT 52353) to APC 0429

Boston Scientific applauds CMS for creating APC 0429 (*Level V Cystourethroscopy and other Genitourinary Procedures*) which facilitates improved clinical and resource coherence for these device-intensive urologic procedures. We offer one modification to the proposed structure, which is to assign one additional procedure, ureterscopic lithotripsy (CPT 52353) to APC 0429. Our justification for this recommendation is presented in our detailed comments.

D. Reassignment of C-code (C9713) from New Technology APC 1525 to APC 0429

Boston Scientific applauds CMS's decision to create APC 0429 but we have concerns about CMS's proposal to include HCPCS code C9713 (*Non-contact Laser Vaporization of the Prostrate*) as part of this APC. As there is not yet sufficient data collected on this procedure, we believe moving C9713 from its current New Technology APC group (New Tech APC 1525) to a clinical APC is premature for CY2006. We recommend keeping HCPCS code C9713 in New Technology APC group 1525 for one more year to allow for more claims to be used in assigning this procedure to a clinically appropriate APC. If CMS is convinced that a reassignment is justified for CY2006, we request that CMS assign C9713 to New Tech APC 1524 (*Level XIV - $3,000-$3,500*) where the payment rate is commensurate with the median costs of single procedure claims for C9713.

E. Creation of Three New APCs for Vascular Access Procedures and Status Indicator Change for Vascular Access Ultrasound Guidance (CPT 76937)

We strongly endorse CMS's creation of three APCs for vascular access device (VAD) procedures (APCs 0621, 0622, 0623) and urge CMS to finalize this proposal for CY2006. These refined groupings will compliment the more precise CPT coding created for these procedures in recent years. In addition, Boston Scientific believes the status indicator for CPT 76937 should be changed from an "N" to an "S" to allow for separate and additional payment for the procedure when performed in conjunction with vascular access procedures. We believe the most appropriate reassignment for ultrasound guidance is APC 0268 (*Ultrasound Guidance Procedures*) with the following proviso: should subsequent cost data for CPT 76937 demonstrate that the $62.69 proposed payment rate represents a significant overpayment, the code would be reassigned to a more appropriate APC as identified by CMS.

Policy Changes Related to Device Pass-through Categories (Section III – pages 16-17)

We applaud CMS for proposing to make important and needed policy changes to the device pass-through payment eligibility criteria. Specifically, we strongly support modifications to the criteria that will change the way CMS currently interprets the surgical insertion and implantation criterion and evaluates requests for new pass-through device categories. We strongly support CMS's proposal to allow creation of a new pass-through payment category for a device where an existing or previously existing category descriptor does not appropriately describe the new type of device if other criteria are met. We request that pass-through applications currently under review be considered in light of the new pass-through category criteria and activated at the start of CY 2006 where the new category criteria are met.

Proposed Requirements for Assigning Services to New Technology APCs (Section IV – pages 17-19)

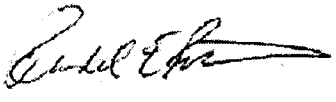
Boston Scientific strongly urges CMS to reconsider and withdraw its proposal to require that a CPT code application be submitted to the American Medical Association (AMA) prior to the submission of an application for a New Technology APC. By doing so, CMS will demonstrate its continued commitment to providing its beneficiaries with access to valuable new technologies, and it will maintain the distinction between reporting mechanisms and coverage. In lieu of using the CPT process as a proxy for physician participation, Boston Scientific recommends CMS appoint a standing advisory committee of clinical representatives from different specialties and hospitals to review and provide input to CMS on New Technology APC applications. Individual members of the committee can provide input and information on the appropriateness of assigning a New Technology APC to new procedures. Such a committee would allow CMS to continue to review applications in a timely manner and provide additional insights from the greater medical community.

****

Thank you again for this opportunity to comment on the OPPS Proposed Rule for CY2006. We remain committed to working with CMS and other affected parties and stakeholders to ensure hospitals and beneficiaries have continued access to our company's wide array of products and technologies that provide effective alternatives to traditional major surgery and other medical procedures that are typically traumatic to the body.

Sarah Wells (202-637-8021; sarah.wells@bsci.com) in our Washington office will follow-up with Jim Hart to confirm receipt of these comments and answer any questions. In the interim, please do not hesitate to contact me at (508-652-7410; randel.richner@bsci.com) if I can be of further assistance.

Sincerely,



Randel E. Richner, BSN, MPH
Vice President, Government Affairs and Reimbursement & Outcomes Planning

cc: Herb Kuhn, Center for Medicare Management, CMS
Tom Gustafson, Center for Medicare Management, CMS
Elizabeth Richter, Hospital and Ambulatory Policy Group, CMS
Jim Hart, Division of Outpatient Care, CMS
Joan Sanow, Division of Outpatient Care, CMS

ATTACHMENT A

I. Device-Dependent APC Concerns

Boston Scientific remains supportive of packaging device costs to calculate payment rates under the prospective payment system for hospital outpatient services. However, we are very concerned about the continued inaccurate reflection of device-related costs in the claims data upon which APC payment rates are based. Hospitals' inconsistent billing practices and underreporting of c-codes, charge compression, CMS's inconsistent use of external data and heavy reliance on "single procedure" and "pseudo single" claims are all contributing to significant APC rate fluctuations from year to year. CY2006 rate-setting based on CY2004 claims (where c-code reporting for devices was optional) poses a unique set of challenges to accurately account for costs in device-related procedures.

While we appreciate CMS conducting a detailed analysis to examine policy options and mitigate significant rate cuts facing device-dependent APCs this year, we have serious concerns about CMS adjusting cost medians downward for 10 device-dependent APCs to 85% of respective cost medians for CY2005. We believe the magnitude of this reduction is too steep. Thus, for CY2006, we urge CMS to implement the recommended APC-specific adjustments described below, or alternatively, to set rates for these APCs at no less than 100% of CY2005 payment rates plus inflation and other update factors applied to all APCs. Beyond CY2006, we urge CMS to implement alternative rate-setting methodologies that more accurately and adequately reflect the costs associated with these and other device-related procedures that would be not be addressed by CMS's proposed policies.

Of particular concern to us are the median cost adjustments proposed for four device-dependent APCs – ***Implantation of Neurological Device*** **(APC 0222)**; ***Cochlear Implantation*** **(APC 0259)**, ***GI Procedures with Stents*** **(APC 0384)**; and ***Cardiac Electrophysiologic Recording/Mapping (0087)***. Detailed comments and policy recommendations for each are presented below:

A. Proposed Payments for Implantation of Neurological Device (APC 0222) and Cochlear Implantation (APC 0259)

Two APCs of particular concern are APC 0222 *Implantation of Neurological Device* and APC 0259 *Level VI Ear, Nose, and Throat Procedures.* In the 2006 Proposed Rule, the payment rate for each of these APCs was adjusted to approximately 85% of their 2005 payment rates. The proposed payment rates if adopted would fall below the hospital acquisition cost for these devices alone and would seriously endanger Medicare beneficiary access to these procedures. Our comments specific to these two APCs of concern follow below.

Payment for Implantation of Neurological Device (APC 0222)
The proposed payment rate for implanted neurostimulators is substantially below the hospital acquisition cost for this device. We believe that the external data submitted to CMS by other manufacturers supports a true hospital acquisition cost of $11,370 during 2004 for the device-dependent component of this APC.

We are greatly concerned that the continued payment reductions proposed for CY2006 will prevent many hospitals from covering their costs, impose significant losses for those hospitals

that perform more of these procedures, and seriously endanger Medicare beneficiary access to this treatment.

Payment for Cochlear Implantation (APC 0259)
Historically, hospitals have been inadequately reimbursed for cochlear implantation under the Medicare program, yet a large body of evidence-based literature strongly supports the value of cochlear implantation for Medicare beneficiaries.

The three cochlear implant manufacturers commissioned The Lewin Group to conduct an empirical study in order to develop recommendations to CMS on appropriate payment levels for cochlear implant procedures. The Lewin Group's analysis demonstrates actual average hospital acquisition costs for cochlear implants of $21,827 during 2004. Based on this information, The Lewin Group's study supports a relative weighting of 458.2168 for APC 0259 and a CY2006 payment rate of $27,192. The Lewin Group's analysis is provided as **Appendix A**.

Recommendations and CMS Requested Action for APC 0222 and APC 0259:

- Use accurate external device cost data and recalculate APC relative weights.
- In lieu of using external data, set the CY 2006 OPPS payment for both APCs no lower than 100% of the 2005 payment rate plus inflation and other update factors applied to all APCs.

B. Proposed Payment for GI Procedures with Stents (APC 0384)

Boston Scientific manufactures and markets many of the stents utilized in GI stenting procedures. As a result, we have watched the progression of payment for APC 0384 with interest since it was introduced in January, 2004. If implemented, the proposal to reduce payment for APC 0384 would be the second significant reduction in payment for this APC since it was introduced, and it would represent a cumulative reduction of 16.5% since CY2004.

CMS's rationale for using all single and pseudo-single claims meeting its edits, regardless of whether a HCPCS code (specifically a c-code) was reported or not, was that utilizing only those claims where c-codes were reported would result in basing payment rates on small numbers of claims and would be unlikely to be representative of hospitals' resource costs. While this may be true for many of the device dependent APCs, Boston Scientific does not agree with CMS's hypothesis as it relates specifically to APC 0384.

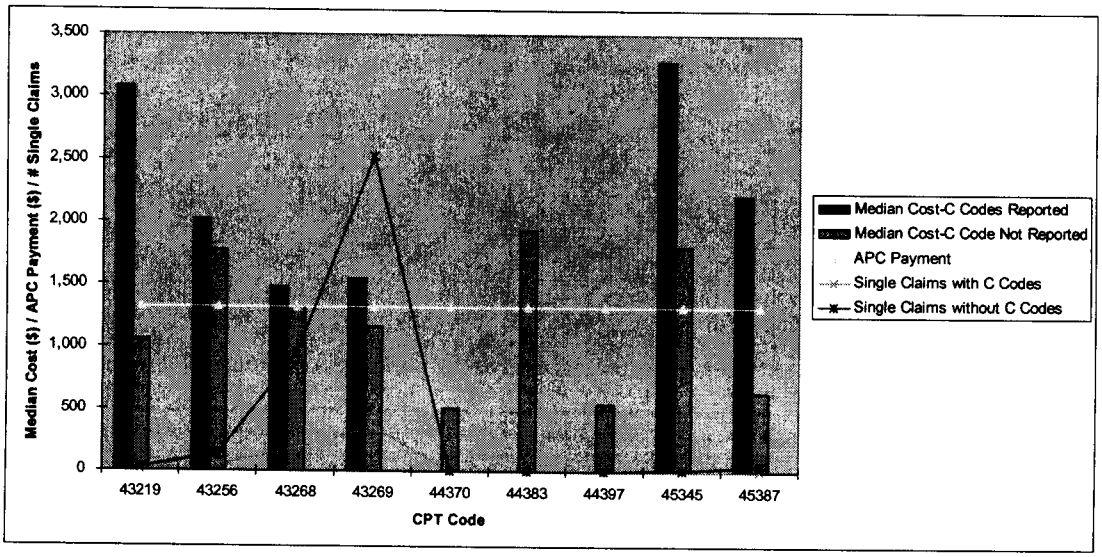
All of the procedures in APC 0384 require the placement of one or more stents. Therefore, by definition, hospitals should be reporting at least one unit of a c-code for each Medicare procedure performed. CMS states that of 20,711 total claims for APC 0384, only 6,268 claims (30%) were single claims or could be utilized as pseudo-single claims. We conducted an analysis of 2004 claims for APC 0384 and noted that, of the 4,294 true single claims available for analysis in the CMS SAS claims data files, 593 claims (13.8%) contained c-codes. More importantly, the median costs associated with those claims containing c-codes were significantly higher than the median costs associated with claims that did not contain c-codes. We believe that the claims containing c-codes are more representative of actual costs, since in many cases when c-codes were not reported, the total resource costs reported by the hospital were less than the cost of a single stent. Boston Scientific is therefore concerned that by utilizing both single and pseudo-single claims that contain c-codes along with those that do not contain c-codes, CMS is significantly under-representing the costs associated with performing the procedures assigned to

APC 0384. See **Table 1** and **Graph 1** below for a summary of our analysis findings.

Table 1:
Comparison of Median Costs for Claims With and Without C-codes for APC 0384

	Claims with C-codes		Claims without C-codes	
CPT Code and Description	**# Claims**	**Median Cost**	**# Claims**	**Median Cost**
43219 Esophagus endoscopy	6	$3,078	29	$1,065
43256 Upper gi endoscopy w/stent	49	$2,018	135	$1,771
43268 Endo cholangiopancreatograph	178	$1,479	952	$1,324
43269 Endo cholangiopancreatograph	355	$1,550	2,522	$1,166
44370 Small bowel endoscopy/stent	.	.	2	$507
44383 Ileoscopy w/stent	.	.	2	$1,932
44397 Colonoscopy w stent	.	.	1	$540
45345 Sigmodoscopy w/stent	3	$3,288	13	$1,803
45387 Colonoscopy w/stent	2	$2,215	45	$640
Total	593		3,701	

Graph 1: APC 0384 – GI Procedures with Stenting, Comparison of Claims With and Without C-Codes



Boston Scientific presented this same analysis to the APC Advisory Panel on August 18, 2005. At that time, Boston Scientific recommended that CMS calculate the median cost for APC 0384 using only those claims containing c-codes. The APC Advisory Panel agreed with our recommendation and advised CMS to utilize only those claims containing c-codes to calculate the median cost for APC 0384. Boston Scientific urges CMS to accept the Panel's recommendation and calculate the CY2006 payment median for APC 0384 using only those claims containing c-codes. Doing so would mitigate additional payment reductions that could hamper beneficiary access to GI stenting procedures, and maintain payment stability during the transition from voluntary to mandatory c-code reporting. Finally, utilization of only those claims containing c-codes is consistent with CMS payment methodology for CY2003 and CY2004.

In the event that CMS rejects the Panel's recommendation, we strongly urge CMS to freeze payments at 100% of the 2005 rate plus inflation and other update factors applied to all APCs as opposed to the proposed 85% floor.

At the August 18, 2005 APC Advisory Panel meeting, the Panel also recommended that CMS create a new APC and move the following two procedures (currently assigned to APC 0384) to the new APC:

- CPT 43268, *Endoscopic Retrograde Cholangiaopancreatography (ERCP) with stent placement;*
- CPT 43269, *ERCP with stent removal and/or replacement.*

The rationale provided for the recommendation was that these two procedures are clinically dissimilar to the other procedures assigned to APC 0384, and that the time required to perform ERCP stenting procedures is significantly less than the time required to perform other GI procedures.

In fact, procedures involving stenting of the gastrointestinal lumen predominantly require deployment of stents across a stenotic region. The area of stenosis is most typically caused by an end stage malignancy and frequently these patients have very limited treatment options. Irrespective of the location to be stented, similar techniques are employed to accomplish the procedure. Specifically, the narrowed region is approached endoscopically, under fluoroscopy. Monitoring contrast is injected to define the stenosis, a guide wire is placed across the region of narrowing under fluoroscopic visualization and then a stent is placed across the narrowing. Under continuous fluoroscopy, the stent is deployed. For all stenting procedures, fluoroscopy is an integral component of the service because the physician cannot visualize the distal stent due to the tumor stenosis (or position within the bile duct) and the x-ray monitoring is needed to insure that the ultimate stent position satisfactorily extends across the entire luminal stenosis. For both biliary (ERCP) and non-biliary stent placement, radio-opaque contrast is injected across the luminal narrowing to verify the extent and assess for any fistulas. In most practices, this injection of contrast is performed with an ERCP-type cannula whether the tumor is within the esophagus, colon, bile duct or elsewhere. Similarly, the guide wires employed in stent placement are the same as those used for ERCP. Thus, stent placement in the biliary tree and elsewhere in the gastrointestinal tract requires similar equipment, supplies, techniques and fluoroscopic assistance.

We respectfully disagree with the committee regarding the clinical differences and duration of these procedures. Rather, we suggest that physician and fluoroscopy time for performance of stent placement is determined more by nuances arising from gaining access across the tumor, sedating the patient and fluoroscopic monitoring rather than the inherent location of the malignancy. The selection inherent in patients offered this service affords a patient population enriched with elderly, cachexic and debilitated individuals, all of whom stand to gain some benefit when non-surgical palliation of their malignant gastrointestinal obstruction occurs. Finally, as illustrated in our data analysis, ERCP stenting procedures account for the largest proportion of claims for procedures assigned to APC 0384. The median cost for APC 0384 is thus likely to be primarily representative of the resources used for ERCP stenting procedures, so it is unnecessary to create a different APC. Therefore, Boston Scientific asks that CMS maintain the current configuration of APC 0384 for CY2006.

In the event that CMS decides to adopt the Panel's recommendation to move the ERCP stenting codes to a new APC code, Boston Scientific requests that CMS also adopt the Panel's recommendation that only those claims where c-codes were reported be used to calculate the median payment rate. Also, consistent with our earlier request, if CMS rejects the proposal to base the rate for APC 0384 only on claims that include the reporting of a c-code, we strongly urge CMS to freeze payments at 100% of the CY2005 rate plus inflation and other update factors applied to all APCs as opposed to the proposed 85% floor.

Recommendations and CMS Requested Action:

- Adopt the APC Panel recommendation to recalculate median cost for APC 0384 using only those claims in which c-codes were reported.
- Maintain the current configuration of APC 0384; that is to say, do not assign ERCP procedures to a new APC as recommended by the APC Panel. Should CMS decide to move ERCP codes to a new APC, use only claims with c-codes to estimate median costs.
- If CMS decides against using "with c-code" only claims in either above case, freeze CY2006 rates at 100% of the CY2005 rate plus inflation and other update factors applied to all APCs as opposed to implementing the proposed 85% floor.

C. Proposed Payment for Cardiac Electrophysiologic Recording/Mapping (APC 0087)

Boston Scientific is very concerned about CMS's proposed payment for APC 0087 *Cardiac EP Recording/Mapping* and the impact of year to year payment volatility on institutions that routinely perform cardiac recording/mapping outpatient procedures.

The (61%) change from CY2005 adjusted to CY2006 unadjusted median costs for this APC is clearly alarming. And while we appreciate the effort made by CMS to adjust the median costs for APC 0087 when setting CY2006 payments, we believe a net payment reduction of 15% is too steep for these procedures that play an important clinical role in the diagnosis and treatment of cardiac arrhythmias. Our evaluation of the OPPS claims data for these procedures suggests that large numbers of hospital claims for these services involved missing or underreported device charges. Given the inherent problems with the CY2004 claims data for this APC, we urge CMS to adjust cost medians further so that the final payment rate is at no lower than 100% of the CY2005 rates plus inflation and other updated factors applied to all APCs.

Recommendations and CMS Requested Action:

- Set the CY2006 payment rate at no lower than 100% of the CY2005 payment rate plus inflation and other updated factors applied to all APCs.

II. APC-Specific Issues of Particular Interest/Concern to Boston Scientific

A. Reassignment of Laminectomy for Implantation of Neurostimulator Electrodes (CPT 63655) from APC 0225 to APC 0040

We noted that some HCPCS codes were moved to different APCs without a discussion in the proposal providing the rationale for the changes. In the future, we urge CMS to include in the proposal a discussion of these changes to afford stakeholders a full opportunity to provide constructive feedback during the comment period.

Of particular concern is the reassignment of CPT 63655 *Laminectomy for implantation of neurostimulator electrodes, plate/paddle, epidural* from APC 0225 *Level II Implantation of*

Neurostimulator Electrodes to ACP 0040 *Level I Implantation of Neurostimulator Electrodes.* This reassignment would represent a 73% drop in payment for CPT 63655. Such a significant decrease in payment would create a significant barrier to access for Medicare beneficiaries. Further, the proposed reduction is so drastic that it may create inappropriate treatment selection incentives without regard to medically appropriate care for Medicare beneficiaries.

A review of the procedures within APC 0040 rank and ordered by median costs in **Table 2** below shows a clear violation of the two times rule with median costs ranging from $2,647.95 for CPT 64555 to $16,032.74 for CPT 64565.

Table 2: Frequency of "Single" Claims and "True" Median Costs for HCPCS Codes Assigned to APC 0040		
CPT/ HCPCS	**"Single" Frequency**	**"True" Median Cost**
64555	122	$ 2,647.95
63650	1596	$ 2,866.51
64580	3	$ 3,362.63
64561	460	$ 3,822.65
64560	2	$ 3,837.47
64581	332	$ 5,501.20
63655	69	$ 5,746.58
64575	26	$ 5,815.60
64565	5	$16,032.74
	APC Median	$ 3,338.79

A more in-depth review of the neurostimulator electrode implantation procedure groups in the proposed rule for APCs 0040 and 0225 identified opportunities to further improve the clinical and cost congruence of these procedure groupings. Based on the above factors, we recommend that CMS restructure APC 0040 and APC 0225 into three distinct APC groups to describe: 1) percutaneous implantation; 2) laminectomy or incision for implantation; and 3) cranial electrode implantation. See **Tables 3-5** on the following page for the specific new APC groupings for neurostimulator electrode implantation that were unanimously recommended by APC Advisory Panel on August 18, 2005.

Table 3: Proposed New Level I APC for Implantation of Neurostimulator Electrodes			
CPT/ HCPCS	**CPT Description**	**2005 APC Assignment**	**"True" Median Cost**
63650	Percutaneous implantation of neurostimulator electrode array, epidural	0040	$ 2,866.51
64555	Percutaneous implantation of neurostimulator electrode array, peripheral nerve	0040	$ 2,647.95
64560	Percutaneous implantation of neurostimulator electrode array, autonomic nerve	0040	$ 3,837.47
64561	Percutaneous implantation of neurostimulator electrode array, sacral nerve	0040	$ 3,822.65
64565	Percutaneous implantation of neurostimulator electrode array, neuromuscular	0040	$16,032.74
		Estimated APC Median Cost	$ 3,086.62

Table 4: Proposed New Level II APC for Implantation of Neurostimulator Electrodes			
CPT/ HCPCS	**CPT Description**	**2005 APC Assignment**	**"True" Median Cost**
63655	Laminectomy for implantation of neurostimulator electrodes, plate/paddle(s), epidural	0225	$ 5,746.58
64575	Incision for implantation of neurostimulator electrodes, peripheral nerve	0040	$ 5,815.60
64577	Incision for implantation of neurostimulator electrodes; autonomic nerve	0225	$11,312.99
64580	Incision for implantation of neurostimulator electrodes; neuromuscular	0225	$ 3,362.63
64581	Incision for implantation of neurostimulator electrodes, sacral nerve	0040	$ 5,501.20
		Estimated APC Median Cost	$ 5,558.05

Table 5: Proposed New Level III APC for Implantation of Neurostimulator Electrodes			
CPT/ HCPCS	**APC**	**2005 APC Assignment**	**"True" Median Cost**
64573	Incision for implantation of neurostimulator electrodes; cranial nerve	0225	$14,510.28
64553	Percutaneous implantation of neurostimulator electrodes; cranial nerve	0225	$12,064.27
		Estimated APC Median Cost	$14,098.18

Recommendation and CMS Requested Action for APC 0225 and APC 0040:

- Adopt the Panel recommendation to reconfigure APC 0040 and APC 0225 into three distinct APC groups as outlined above.

B. Designation of Non-Coronary Intravascular Ultrasound (IVUS) (CPT 37250/APC 0416/C1753) as "Device-Dependent" and Claims Selection Methodology for Estimating Device-related Costs

Designation of Non-Coronary IVUS as "Device-Dependent"

Boston Scientific remains concerned that neither CPT 37250 *Intravascular ultrasound (non-coronary vessel) during diagnostic; initial vessel* (non-coronary IVUS), nor the APC to which it is currently assigned (APC 0416 *Level I Intravascular and Intracardiac Ultrasound and Flow Reserve*), are currently designated as "device-dependent" under OPPS. Failure to recognize this truly "device-dependent" procedure contributes to the inaccurate median cost estimation of this adjunctive outpatient procedure.

On August 18, 2005, the APC Advisory Panel recommended that APC 0416/CPT 37250/C1753 be added to the list of device dependent edits. Boston Scientific urges CMS to act on this recommendation as soon as possible as a first step to improving data capture of the device-related costs for non-coronary (peripheral) IVUS for future APC rate setting.

We also would like to respond to the discussion at the APC Advisory Panel on August 18th concerning the reassignment of non-coronary IVUS, initial vessel (CPT 37250) to APC 0670 (*Level II Intravascular and Intracardiac Ultrasound Flow and Reserve*), the APC where coronary IVUS, initial vessel is grouped. While we appreciate the statements made by CMS and the APC Advisory Panel that such a reassignment may duplicate the radiological supervision and interpretation (S&I) component of this procedure, we believe that CPT 37250 should be appropriately grouped with other clinically similar device-dependent procedures. With this in mind, we ask CMS to continue to monitor the resource use of CPT 37250 relative to other procedures assigned to APC 0416 to determine whether potential reassignment is warranted for CY2007.

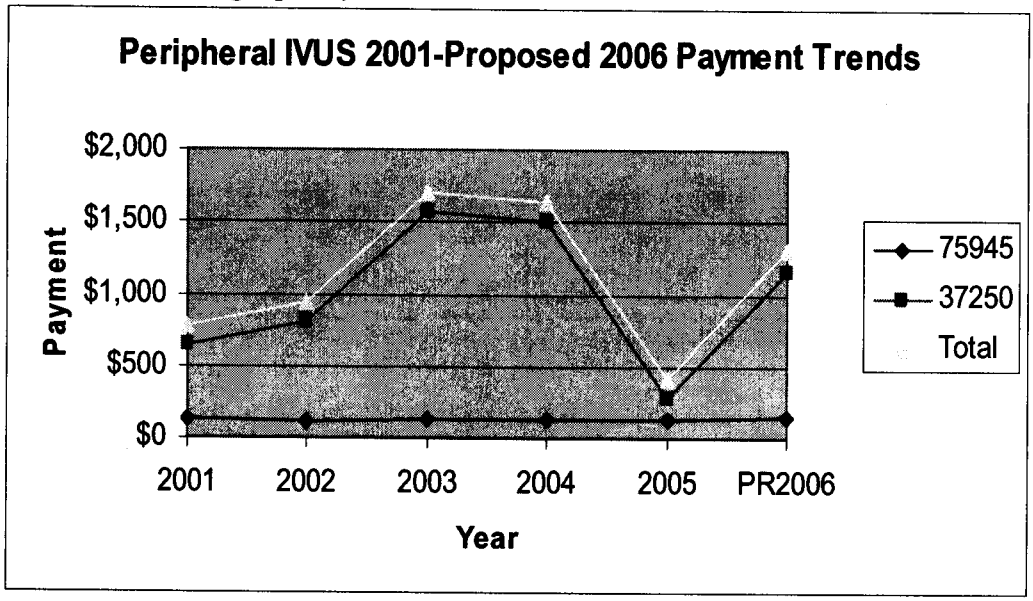
Claims Selection Methodology for Estimating Device-related Costs

Boston Scientific also is very concerned about the method CMS is using for claims selection to estimate costs for separately payable adjunctive procedures reported using "add-on" CPT codes. Non-coronary IVUS is one such procedure that is particularly disadvantaged by this methodology.

Because non-coronary IVUS procedures are always reported in conjunction with other separately payable procedures, the claims for these procedures are considered "multiple major" under CMS's methodology and thus are not used in rate-setting. The volume of "single" and "pseudo single" claims CMS does use are not at all reflective of the actual provision of this service to Medicare beneficiaries in the outpatient setting. The limited number of claims only exacerbates the inaccurate capture of the resources utilized in this procedure.

As illustrated in **Graph 2** on the following page, this methodology consequently has led to high payment volatility for non-coronary IVUS procedures from year to year but the S&I component of the procedure (CPT 75945) has remained fairly stable and is not a key driver in the increase in the total payment pool of dollars.

Graph 2: Payment Trends for Non-Coronary (Peripheral) Intravascular Ultrasound, CY2001 to CY2006 (proposed)



Shortcomings of Using "Pseudo" Claims for Median Setting

To better understand why the claims data substantially underestimate the costs associated with separately payable "add-on" procedures such as non-coronary IVUS, Boston Scientific commissioned an analysis examining CY2003 and CY2004 claims data.

Our premise going into the analysis was that CMS's algorithm would screen out *all* correctly coded non-coronary IVUS claims, and therefore exclude essential claims for APC rate-setting purposes. Our analysis findings (see **Table 6** below) affirm this premise, demonstrating that indeed a small percentage of single claims drive the gross under-estimation of non-coronary IVUS costs and lead to inadequate payment for this procedure.

Table 6
Comparative Analysis of Claims Used to Calculate OPPS Rates for Non-Coronary IVUS

2004 Claims Data Highlights	2003 Claims Data Highlights
• "Pseudo" single claim algorithm screens out over 98% IVUS claims • 19 claims counted out of 1,206 (2%) • 57% of the 19 claims show device revenue center -Lower median costs on claims with no devices	• "Pseudo" single claim algorithm screens out over 96% IVUS claims • 39 claims counted out of 916 (4%) • 59% of the 19 claims show device revenue center -Lower median costs on claims with no devices

Source: Direct Research, LLC analysis of 2005 & 2006 Proposed Rule OPPS LDS file.

Suggested Alternative Methodology for Selecting Multiple Procedure Add-on Claims

When a claim shows two devices, it should be considered correctly coded, and then CMS should split the claim and associate each of the devices with the relevant APC. For example, consider a

claim containing both non-coronary IVUS and non-coronary balloon angioplasty. To be included in the weight calibration algorithm, such a claim would be required to have both a c-code for the balloon angioplasty device, and one more device(s) or charges that would plausibly account for the IVUS catheter under C1753.

In effect, because the procedure combination requires two devices, we would expect the claim to show two devices and to be considered correctly coded. Then, in splitting the claim, CMS would associate the balloon catheter device with the balloon angioplasty APC, associate the other device or device revenue center costs with the IVUS APC, and proceed to split the claim. If no other packaged revenue centers appeared, the claim would be split into two single procedure claims, associating each device with the relevant procedure.

While it is possible that only a minority of claims would pass this screen, it should be kept in mind that only about two to four percent of non-coronary IVUS claims pass the current single-procedure algorithm, and the majority of these are incompletely coded claims with no devices or device-related costs reported on the claim. Although we have no way to test this approach currently, we believe that it is unlikely to do worse than the current method and should better reflect overall procedure and device costs.

Even with the aforementioned edit in place, the single claims methodology will continue to be problematic for payment rates for procedures that are always done in conjunction with other procedures. The need for a methodology to best reflect total procedure costs remains a challenge and we believe aligning device costs via c-codes will assist in this quest.

In summary, Boston Scientific believes the expected outcome of incorporating our policy recommendations will allow payment for non-coronary IVUS to be more accurately evaluated and assigned to a clinically comparable and resource cohesive APC. The potential consequences of no change will result in the hospital experiencing APC payment fluctuation based on an extremely small percent of the claim pool that most likely does not reflect resource utilization associated with the procedure. This may mean non-coronary IVUS will not be utilized on beneficiaries as needed.

Recommendations and CMS Requested Action:

- Add to CPT 37250/C1753 to device edits or device-dependent APCs (Table 15 in the proposed rule) as recommended by the APC Panel in the August 18, 2005 meeting.
- Monitor CPT 37250 for appropriateness of APC reassignment in CY2007.
- Develop an alternative methodology for multiple procedure add-on claims with device(s).

C. Reassignment of CPT code 52353 to APC 0429

In the proposed rule, CMS created APC 0429 (*Level V Cystourethroscopy and other Genitourinary Procedures*). This new APC would hold a higher level of more device-intensive urologic procedures, including laser surgery treatments for benign prostatic hyperplasia (BPH) and percutaneous nephrostolithotomy (PCNL).

We applaud the creation of this new APC, as it will better align payment rates for these cystourethroscopic procedures with the resources they consume. These resources include capital equipment (laser consoles, cystoscopes and nephroscopes) and a wide range of single-use devices

(ureteral balloon catheters, dilators, introducer needles, guidewires, drainage tubes and laser fibers for breaking up kidney stones or vaporizing and/or coagulating prostate tissue.)

We would only recommend that CMS add the following code to APC 0429:

CPT 52353 - *Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with lithotripsy (ureteral catheterization is included)*

Moving CPT 52353 (ureteroscopic lithotripsy) to the newly created APC 0429 is justified based on the following reasons:

1. CPT 52353 closely matches the other procedures in APC 0429 in terms of resource utilization and clinical homogeneity. This is evidenced by the fact that CMS has grouped ureteroscopic lithotripsy for almost four years (2002 through 2005) with all the urology codes slated for assignment to APC 0429 (CPT codes 50080, 50081, 52647 and 52648). Given the extensive resource and clinical coherence of ureteroscopic lithotripsy with the other codes proposed for assignment to APC 0429, it should not be excluded from the other very similar procedures moving to APC 0429.

2. By definition, CPT 52353 requires a cystoscope (about $8,000) and a holmium laser console (about $130,000) which provides the energy used in intracorporeal lithotripsy to break up kidney stones. These pieces of capital equipment are also used with the BPH laser surgery and PCNL procedures in APC 0429. Ureteroscopic lithotripsy also requires the use of a ureteroscope (about $15,000), making it all the more resource-intensive. The holmium laser used in ureteroscopic lithotripsy has been revolutionary in the treatment of kidney stones, as it is extremely effective in fragmenting all varieties of stones in a minimally invasive fashion. Like the other codes (BPH laser surgery and PCNL) in APC 0429, ureteroscopic lithotripsy uses a wide range of single-use medical devices, including balloon dilatation catheters, ureteral sheaths, guidewires, ureteral catheters, stone retrieval baskets and laser fibers. The total combined per procedure costs of these single-use devices alone can be well over $800, which is separate from the capital equipment and other hospital costs of providing this procedure.

3. Like the PCNL procedures in APC 0429, ureteroscopic lithotripsy is performed on patients suffering from urinary stones lodged in the kidney and/or ureter by directly accessing the stone and pulverizing it via intracorporeal lithotripsy.

4. Ureteroscopic lithotripsy enjoys very high clinical outcomes, but can be costly due to the need for frequent repairs of the ureteroscope. Research shows that flexible ureteroscopes only can be used only 6 to 15 times before requiring expensive maintenance repairs to recondition the ureteroscope. A study published in the August 2003 issue of Urology showed a range of maintenance costs of $31,520 to $60,033 for 100 cases using different brands of ureteroscopes.[1] This averages to a per procedure maintenance cost of $315-$600. It is likely most hospitals are not accurately capturing the cost of these ureteroscope repairs when developing their OR charges, as most hospitals set their OR charges based on time and capital equipment costs, not on the maintenance costs for certain equipment. This suggests the OPPS median cost claims data on CPT 52353 may well underestimate the actual costs of this

[1] Landman J, Lee D, Lee C, Monga M. Evaluation of Overall Costs of Currently Available Small Flexible Ureteroscopes. Urology 62: 218-222 ©2003 Elsevier Inc.

procedure by some $315-$600. With OPPS median cost for CPT code 52353 in 2004 at $2,150, actual costs incurred by hospitals for ureteroscopic lithotripsy may be closer to $2,465 to $2,750.

5. Even with the maintenance costs for ureteroscopes not likely being charged by hospitals, ureteroscopic lithotripsy still has the highest median cost ($2,150) of the nine procedures in CMS's proposed grouping of APC 0163 (*Level IV Cystourethroscopy and other Genitourinary Procedures*). This is not enough on its own to justify a change but it shows that it already is on the cusp of the next level APC.

6. Moving CPT 52353 to APC 0429 would have a negligible impact on the median costs of APCs 0163 and 0429. The median cost of APC 0163 would fall by only $19 to $2,016, while APC 0429's median costs would drop by about $100 to $2,457. Thus, other codes in APC 0163 and 0429 would not experience any payment disruptions, so there should not be any concern about unintended consequences of making this change.

Recommendation and CMS Requested Action:

- Reassign CPT 52353 from APC 0163 to the newly created APC 0429 (*Level V Cystourethroscopy and other Genitourinary Procedures*).

D. Reassignment of HCPCS code C9713 from New Tech APC 1525 to APC 0429

CMS proposes to move the following new technology service billed under HCPCS code C9713 (*Non-contact laser vaporization of prostate, including coagulation control of intraoperative and post-operative bleeding*) to the newly created APC 0429 (*Level V Cystourethroscopy and other Genitourinary Procedures*).

While we applaud the creation of APC 0429 for other cystourethroscopy procedures, we are extremely concerned that CMS's proposal to assign C9713 to APC 0429 is premature, as the move would be based on only nine months of claims data, an insufficient time to justify its removal from New Technology APC 1525.

The reasons for keeping C9713 in New Tech APC 1525 are as follows:

1. CMS is basing its reassignment to a clinically appropriate APC based on only nine months of OPPS claims, as the HCPCS code C9713 became effective on April 1, 2004. This contrasts markedly from new technology PET scans in the G0211-G0234 series that have resided in various New Tech APCs for at least four years (2002-2005). Moreover, the Program Transmittal detailing this new HCPCS code was not released until 3/30/04, with an 4/5/04 implementation date, so it is extremely unlikely that most hospitals even knew of this code for some time after its creation, meaning that the claims CMS has for C9713 are probably for much less than nine months of data.

2. At the August 2005 APC Advisory Panel, a presentation was made on this issue, prompting discussion about hospitals' inconsistency in using the appropriate code for this procedure. Several Panel members said their hospitals were incorrectly coding these procedures and raised questions about the accuracy of the claims data. While the Panel ultimately agreed with CMS's proposal to move C9713 to APC 0429, this was based on an expectation that this

code would end up in this APC anyway, not on agreement that the OPPS data for C9713 was accurate.

3. Removing C9713 from APC 0429 would only slightly shave APC 0429's median cost by $19 to $2,534. This minimal impact ensures that procedures remaining in APC 0429 (PCNL, BPH Laser Surgery) would not be adversely impacted by the removal of C9713.

4. Finally, under CMS's proposal, the payment rate for C9713 would fall by about 33%, from $3,750 to $2,511. We are concerned that this represents too much of an abrupt cut that could pose patient access concerns. It is also inconsistent with CMS efforts to mitigate payment reductions for device-related APCs. In the proposed rule, CMS places a 15% floor on the reduction in the median costs for device-dependent APCs in an effort to prevent dramatic cuts from year to year. If CMS is convinced that a reassignment is justified, we ask the Agency reassign C9713 to another New Tech APC, such as New Tech APC 1524 ($3,000 to $3,500). This would be a less drastic step, given that C9713 has only nine months of claims data, and the median cost of single procedure claims for C9713 is $3,066 when screening claims to exclude those without medical device revenue center codes and device costs under $600.

Recommendations and CMS Requested Actions:

- Keep HCPCS code C9713 in New Tech APC 1525 for one more year to allow for more claims data to be used in assigning this procedure to a clinically appropriate APC.
- If keeping C9713 in New Tech APC 1525 is not an option, reassign C9713 to New Tech APC 1524 (*Level XIV - $3,000-$3,500*) for CY 2006, as this tempered step would recognize that CMS has only nine months of claims data, and that C9713's median cost of single procedure claims is $3,066 using conservative device screens.

E. Status Indicator Change for CPT Code 76937 and Creation of Three New APCs for Vascular Access Procedures.

In the proposed rule, CMS recommended the creation of three APCs for vascular access device (VAD) procedures:

- 0621- Level I Vascular Access Procedures
- 0622- Level II Vascular Access Procedures
- 0623- Level III Vascular Access Procedures

We applaud CMS for this important step that demonstrates the Agency's commitment to proper grouping and payment for VAD insertions and related procedures. These refined groupings will compliment the more precise CPT coding created for these procedures in recent years. We urge CMS to finalize these proposals for CY2006.

Furthermore, we support the assignment of the various vascular access procedures to these newly created APCs as outlined in Table 13 of the OPPS proposed rule. It is evident by analyzing 2004 Medicare median cost data for these procedures that these new APC assignments and related payments will more accurately and adequately cover their associated hospital outpatient costs.

Status Indicator of Ultrasound Guidance for Vascular Access Insertions
On January 1, 2004, CPT code 76937 (ultrasound guidance for vascular access insertion[2]) became effective and was assigned a status indicator (SI) of "N", an incidental service packaged under the OPPS system. When this procedure is performed in the hospital outpatient setting, no separate or additional payment is rendered.

Procedural Overview
Ultrasound guidance is used for patients requiring peripherally inserted central venous catheter (PICC) placement, where the physician determines that ultrasound guidance is necessary for safe access. Potential access sites are evaluated, selected and documented, while adjacent structures (artery, nerves, etc.) can be safely visualized and avoided. Finally, the catheter is placed and proper placement is verified using guidance.

Clinical and Cost Rationale
- According to the Agency for Healthcare Research and Quality (AHRQ), the use of ultrasound to guide vascular access is one of the eleven most highly rated clinical practices to improve patient safety.[3]
- AHRQ also concluded that there is a 78% relative risk reduction when ultrasound guidance is used for central venous catheter (CVC) insertions.
- The report cited the lack of additional payment for capital equipment investment as a hurdle to the adoption of this procedure.

Background
Prior to 2004, ultrasound guidance for vascular access procedures was billed using CPT code 76942 *Ultrasound guidance for needle placement*[4]. This code maps to APC 0268 *Ultrasound Guidance Procedures*, triggering a $67 payment to the hospital outpatient facility under the CY2005 OPPS. The new CPT code 76937 would also seem to be an excellent fit within APC 0268 based on the CMS principle of clinical homogeneity as illustrated in **Table 7** on the following page.

[2] The full text descriptor for CPT code 76937 is *Ultrasound guidance for vascular access requiring ultrasound evaluation of potential access sites, documentation of selected vessel patency, concurrent real time ultrasound visualization of vascular needle entry, with permanent recording and reporting (List separately in addition to code for primary procedure.)*
[3] Shojania KG, Duncan BW, McDonald KM, et al., eds. Making Health Care Safer: A Critical Analysis of Patient Safety Practices. Evidence Report/Technology Assessment No. 43.
[4] The full text descriptor for CPT code 76942 is *Ultrasonic guidance for needle placement (eg, biopsy, aspiration, injection, localization device), imaging supervision and interpretation.*

Table 7: HCPCS Codes Assigned to APC 0268 - Ultrasound Guidance Procedures	
CPT Code	**Narrative**
76930	Ultrasonic guidance for pericardiocentesis, imaging supervision and interpretation
76932	Ultrasonic guidance for endomyocardial biopsy, imaging supervision and interpretation
76936	Ultrasound guided compression repair of arterial pseudoaneurysm or arteriovenous fistulae (includes diagnostic ultrasound evaluation, compression of lesion and imaging)
76940	Ultrasound guidance for, and monitoring of, visceral tissue ablation
76941	Ultrasonic guidance for intrauterine fetal transfusion or cordocentesis, imaging supervision and interpretation
76942	Ultrasonic guidance for needle placement (eg, biopsy, aspiration, injection, localization device), imaging supervision and interpretation
76945	Ultrasonic guidance for chorionic villus sampling, imaging supervision and interpretation
76946	Ultrasonic guidance for amniocentesis, imaging supervision and interpretation
76948	Ultrasonic guidance for aspiration of ova, imaging supervision and interpretation
76950	Ultrasonic guidance for placement of radiation therapy fields
76965	Ultrasonic guidance for interstitial radioelement application

Issue Presented Before the APC Advisory Panel

This issue was presented at the August 2005 APC Advisory Panel Meeting. The Panel discussed the issue extensively and seemed sympathetic to the merit of separate payment for ultrasound guidance based on its ability to improve patient safety and clinical outcomes. However, they deferred a decision by requesting that CMS collect available hospital claims data on CPT 76937 for further consideration by the Packaging Subcommittee by the next scheduled meeting.

The Panel seemed to echo previously stated concerns by CMS that separate payment for the ultrasound guidance would foster inappropriate utilization. Given the AHRQ findings, we believe that CMS should be encouraging utilization of ultrasound guidance for vascular access procedures via separate and appropriate payment. The Panel also seemed concerned that APC 0268 may overpay for the type of ultrasound guidance in question. Given that the proposed 2006 payment rate for APC 0268 is $62.69 (its lowest level ever); we do not believe that this is a valid concern.

We do believe that the Panel recommendation will result in an unnecessary delay of at least a year in re-establishing separate payment for this clinically advantageous technology. We therefore urge CMS to reassign CPT code 76937 to APC 0268 with the proviso that should subsequent cost data for code 76937 demonstrate that the $62.69 payment rate represents a significant overpayment, the code would be reassigned to a more appropriate APC as identified by CMS. We believe that this solution would satisfy the concerns of both the Advisory Panel and CMS staff, while making this care-enhancing service more readily available to Medicare Beneficiaries.

Recommendation and CMS Requested Action:

- Change the SI for CPT code 76937 from an "N" to an "S" effective January 1, 2006.
- Assign CPT code 76937 to APC 0268 *Ultrasound Guidance Procedure* to allow for separate and additional payment for the procedure when performed in conjunction with vascular access procedures with the proviso that should subsequent cost data for CPT 76937 demonstrate that the $62.69 payment rate represents a significant overpayment, the code would be reassigned to a more appropriate APC as identified by CMS.

III. Policies Related to Pass-through Device Categories

A. Proposed Modification to Surgical Insertion and Implantation Criterion

Boston Scientific commends CMS for revisiting its surgical insertion and implantation criterion for establishing a new device category and proposing to consider eligible:

"those items that are surgically inserted or implanted either through a natural orifice or a surgically created orifice (such as through an ostomy) as well as those that are inserted or implanted through a surgically created incision." (page 42721 of the Proposed Rule)

We strongly endorse this important and needed policy change which will now enable innovative and less invasive technologies, particularly in the areas of gynecologic, urologic, colorectal and gastrointestinal procedures, to be considered for device pass-through payment status. We therefore urge CMS to adopt this proposal and make it effective January 1, 2006.

Recommendation and CMS Requested Action:

- Adopt and make effective January 1, 2006 the CMS proposal to expanding surgical insertion and implantation criterion for establishing a new device category.

B. Criteria for Establishing New Technology Pass-through Device Categories

Boston Scientific supports CMS's efforts to ensure that Medicare beneficiaries have timely access to new medical treatments that are well-evaluated and demonstrated to be effective. In particular, we applaud CMS's proposed enhancements to the pass-through payment criteria, specifically, to make new technology accessible to its beneficiaries through the modification of an existing or previously existing pass-through device category criterion.

It is important to establish pass-through payments for new device technologies that provide a substantial clinical improvement for Medicare patients and which are not clearly described in an existing or previously existing category. Such decisions have a significant impact on Medicare patient access to beneficial new medical technologies.

For example, the previously existing device category for implantable neurostimulator generators (C1767) does not appropriately describe rechargeable IPG technology. The previously existing category descriptor is overly broad, and was never intended to describe rechargeable IPG technology that did not exist at the time the category was created.

Rechargeable IPG neurostimulators represent a major advancement in medical technology that has important technological differences versus existing non-rechargeable IPG's and external RF-transmitter systems. We are pleased that CMS recently determined in the FY2006 Inpatient Prospective Payment System Final Rule that rechargeable IPGs provide a substantial clinical improvement over previous technologies. However, for Medicare patients to have access to this

treatment, it is important for this technology to be appropriately considered for pass-through payment.

We support CMS's proposal to create an additional category for devices that meet all of the criteria required to establish a new category for pass-through payment in instances where an existing or previously existing category descriptor does not appropriately describe the new type of device, and request that CMS implement this policy change effective January 1, 2006. Further, we request that pending pass-through applications be considered in light of this new pass-through category criteria, and where the new category criteria are met, make category modifications deemed appropriate also effective January 1, 2006.

Recommendation and CMS Requested Action:

- Adopt and make effective January 1, 2006 the CMS proposal to revise the pass-through device category criterion which would allow the creation of new pass-through device categories where an existing or previously existing category descriptor does not appropriately describe the new type of device.
- Make device category modifications for pending pass-through applications that meet all new category eligibility criteria effective January 1, 2006.

IV. Proposed Requirements for Assigning Services to New Technology APCs

Boston Scientific applauds CMS's efforts to ensure that Medicare beneficiaries have timely access to new medical treatments and technologies and promoting greater interaction and review of new technologies by the greater medical community. However, we strongly urge CMS to reconsider its proposal to require that a CPT code application be submitted to the American Medical Association (AMA) prior to the submission of an application for a New Technology APC. The submission of a CPT code application will not enable CMS to meet its stated objective of "promoting review of the coding, clinical use, and efficacy of new technology services by the greater medical community." Moreover, elements of the CPT application process may result in unanticipated and significant negative ramifications for both providers and developers of new technologies. In lieu of using the CPT process as a proxy for physician participation, Boston Scientific recommends that CMS appoint a standing advisory committee of clinical representatives from different specialties and hospitals to review and provide input to CMS on New Technology APC applications.

CPT Requirement Does Not Promote Review by the Greater Medical Community

The requirement that a CPT application be filed, in and of itself, will not provide CMS with input from the greater medical community unless CMS is proposing to wait until the AMA CPT Editorial Panel has made a coding determination and that determination has been made public. Filing an application neither requires nor guarantees a review by the greater medical community. In addition, the CPT code application will not provide CMS with additional information on the technology being evaluated, beyond what is provided as part of the New Technology APC application process, because the applications are very similar. Moreover, because of the timing of the CPT process, it is not reasonable for CMS to wait until a CPT coding decision has been made public to decide whether to assign a New Technology APC. It can take as long as 6-12 months from submission of an application to an internal Editorial Panel decision on a CPT code application, and the decision is not made public immediately. It can take anywhere from 6 to 24 months from the time an application is submitted until the time a coding decision regarding a

Appendix A

The LEWIN GROUP

Analysis of Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates for Cochlear Implantation Devices/Systems

Prepared for:

Advanced Bionics, Cochlear Americas, and Med-El Corporation

Prepared by:

The Lewin Group, Inc.

September 7, 2005

Analysis of Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates for Cochlear Implantation Devices/Systems

Prepared for:

Advanced Bionics, Cochlear Americas, and Med-El Corporation

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September 7, 2005

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I. INTRODUCTION

Three years ago, The Lewin Group was commissioned separately by Advanced Bionics, Cochlear Americas, and Med-El Corporation to provide technical assistance in assessing the methodology used by The Centers for Medicare & Medicaid Services (CMS) to develop the proposed CY 2003 payment rates for cochlear implant devices/systems. The Lewin Group's initial analysis found that the proposed payment did not reflect the actual cost of the device, largely due to provider miscoding of the device. Next, Lewin recalculated the median Ambulatory Payment Classification (APC) cost by substituting a weighted average selling price that had been individually provided by manufacturers for the device cost found on the claims. Ultimately, in the Final Rule, the APC payment rate better reflected the cost of the device to hospitals as well as outpatient facility costs associated with the device procedure.

In 2004, Advanced Bionics, Cochlear Americas, and Med-El Corporation again separately commissioned The Lewin Group to replicate CMS' methodology and the proposed payment rate for cochlear implant devices/systems (APC 0259). On August 16, 2004 CMS published the proposed rule entitled Proposed Changes to the Hospital Outpatient System and Calendar Year 2005 Payment Rates in the *Federal Register.* Because hospitals had additional experience with coding under the Hospital Outpatient Prospective Payment System (OPPS) and because more data on hospital charges were available from CY 2003 claims, it was hypothesized that the proposed CY 2005 payment rate would more adequately reflect actual hospital costs for the APC. In this NPRM, CMS proposed an APC payment of $23,686 for CY 2005, with a final payment subsequently set at $25,307.

Once again, in 2005, The Lewin Group was commissioned to replicate CMS' methodology underlying the proposed payment rate for cochlear implant devices/systems (APC 0259). On July 18, 2005 CMS published a NPRM containing the proposed payment rate of $21,739 for APC 0259 for CY 2006, a fourteen percent decrease from the CY 2005 final payment rate of $25,307.

In replicating CMS' analysis of CY 2004 OPPS claims data, we found the median cost of APC 0259 to be $21,046, with a median device cost of $16,408. There is a large discrepancy between the median device cost in the CY2004 OPPS claims and the industry average selling price of $21,827. Lewin analysis of the CMS claims clearly demonstrates that the CMS proposed payment for CY2006 is not economically viable for the hospitals or the manufacturers of cochlear implant devices/systems, as it does not cover facility costs.

II. SUMMARY OF RESULTS & FINDINGS

- There is a large discrepancy between the median device cost derived from the CY 2004 OPPS claims ($16,408) and the average selling price (device list price net of discounts) of $21,827.

- CMS proposed a budget neutral, adjusted APC payment of $21,739 for CY 2006. Lewin duplicated CMS' analysis using the industry average selling price for the device and recalculated the median APC cost as $25,743, which is slightly more than the CY2005 payment of $25,307.

- The Lewin Group calculated a budget neutral APC payment of $27,192 which reflects the actual cost of the device and the hospital facility costs associated with the cochlear implantation procedure.

- The proposed payment rate for cochlear implant devices/systems is economically unsustainable, and would disadvantage Medicare beneficiaries by reducing access to cochlear implant devices/systems.

III. ANALYTIC METHODS

A. Overview

Before performing the analyses, Lewin had to create the working dataset from the CY 2004 Outpatient Prospective Payment System limited dataset of hospital outpatient claims (claims for January 1, 2004 - December 31, 2004 which were final as of July 20, 2005). To create the working dataset, Lewin applied the methodology described by CMS in the proposed rule to remove "multiple procedures" claims, leaving claims with a single APC related to CPT 69930 (cochlear device implantation). We then created "pseudo" single claims from the previously removed multiple procedure claims by applying the methodology described in the *Federal Register.*

First, bypass codes (*Federal Register,* July 25, 2005, Table 1) were eliminated from the claims. Next, date of service matching was used to create additional "pseudo" single claims. Single and "pseudo" single claims were then combined to create the APC working dataset. (See ***Figure 1*** on page 5.) To finalize the APC working dataset, non-packaged HCPCS codes (codes without a status indicator of "N") and non-packaged revenue codes (*Federal Register,* July 25, 2005, Table 2) were removed from the claims.

With the working dataset finalized, the first objective of our analysis was to determine the CY 2004 median cost for APC 0259. To estimate the median APC cost, we totaled the costs of the device and procedure as well as packaged HCPCS (codes **with** a status indicator of "N") and packaged revenue codes (*Federal Register,* July 25, 2005, Table 2) for each claim. Finally, we computed the median APC 0259 cost for all single and pseudo-single claims in our working dataset.

Our second objective was to determine the CY 2004 median cost of the device from the claims in our APC working dataset. In 2004, providers were not required to list the device separately on claims; therefore, a two step process was used to identify device costs. First, device costs for claims listing L8614 were identified. Second, on the remaining claims, we examined revenue codes 0270, 0272, 0274, and 0278 to identify additional devices that had not been separately coded. These revenue codes were selected for examination because the device, L8614, was frequently coded to these revenue centers when separately listed. (See ***Figure 2*** on page 6.) A device unit cost was computed for each claim and the median device cost was determined.

Our final objective was to recalculate the APC median and to determine a "new" budget neutral APC payment rate using a weighted average selling price (device list price net of discounts). We first calculated the weighted average selling price using confidential hospital invoice data supplied separately by each of the three manufacturers. The three manufacturers together represent 100% of the cochlear device market nationally. We then substituted the weighted average selling price for the device cost in the CY 2004 OPPS claims and recalculated an APC cost based on this information. Finally, we compared Lewin-derived APC costs (using the weighted average selling price) to APC costs derived from the CY 2004 OPPS claims. We used the median ratio to adjust the relative weight for the procedure and then calculated a "new" CY 2006 APC payment amount by multiplying the "new" relative weight by the conversion factor.

B. Detailed Methods Discussion

1. Creating the Working Dataset

Our first step in creating a working dataset was to extract all claims involving CPT code 69930 (cochlear device implantation) and/or L8614 (the device code) from among the approximately 54.6 million records in the Limited Dataset (LDS) of OPPS claims for CY 2004. This initial dataset contained a total of 962 claims. Claims that had the device L8614 coded, but did not have the corresponding CPT code for cochlear implantation, 69930, were then excluded. This created our original APC dataset, which included 939 claims.

Next, we used the methodology described by CMS in the proposed rule to eliminate multiple procedure claims and to create "pseudo" single claims from our original dataset, leaving only claims with a single APC related to CPT 69930. Two types of multiple major procedure claims were removed from the file:

- Claims in which ancillary costs cannot be associated with individual HCPCS codes because they are supportive of some or all services furnished to the patient - therefore, all claims with more than one procedure showing a status indicator of "S", "T", "V", or "X" were excluded; and
- Claims with packaged HCPCS codes coded with status indicator "N" that include more than one primary procedure (status code "S" or "T") were excluded.

In summary, in this step we extracted all of the singleton claims having only one primary procedure that could be grouped to an APC (aside from laboratory and incidentals such as packaged drugs and venipuncture). Claims could include HCPCS codes with status indicators "A," "C," "E," "G," "H," or "N," as long as there was a single primary procedure within a single APC. We also eliminated claims having a single procedure code but a zero charge. This step resulted in a dataset containing 280 true single procedure claims.

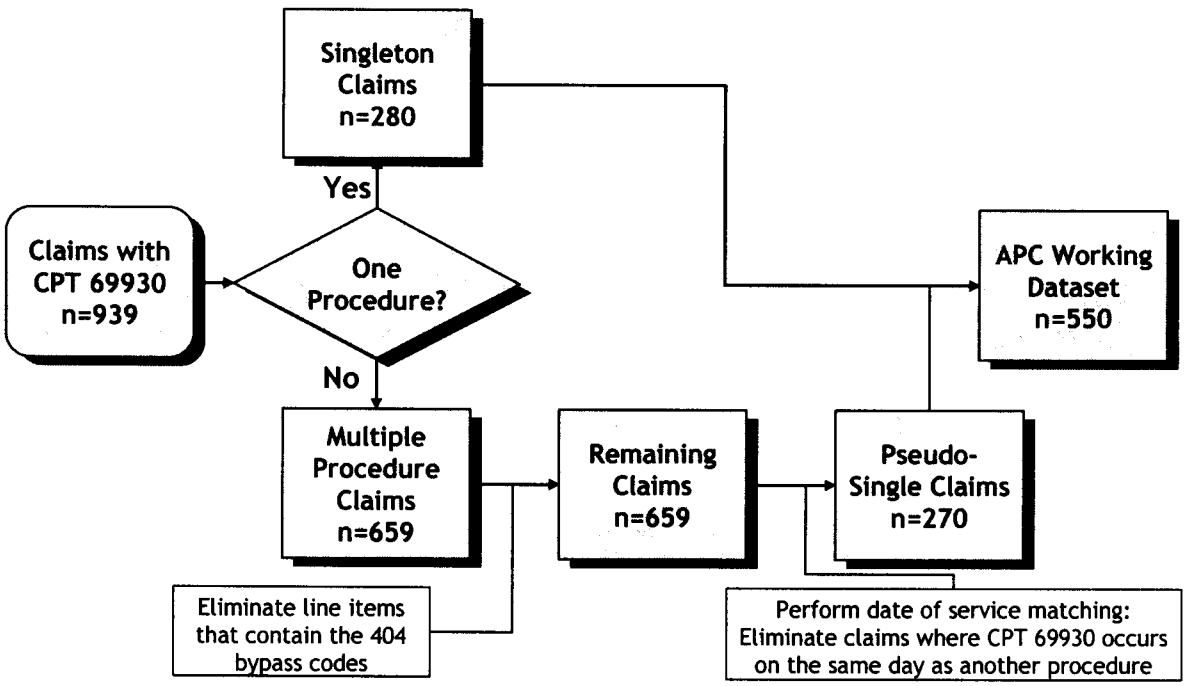
After true singletons were identified, the multiple procedure claims were evaluated to identify "pseudo" single claims. The first step in extracting "pseudo" single claims from multiple procedure claims is to eliminate line items that contain CMS' bypass codes. The bypass codes are procedure codes found to include no packaged costs and their individual costs can, therefore, be eliminated from claims with CPT 69930. Included on this list of bypass codes were chest x-ray codes (HCPCS 71010 or 71020) and an EKG code (HCPCS 93005).

Next, the dates of service were examined on the multiple procedure claims. Ultimately, "pseudo" single claims are those on which multiple procedures occur but the dates of service are different for all procedures. In this case, a multiple procedure claim would have CPT 69930 on one date of service, but different procedures on other dates of service. To create "pseudo" single claims from multiple procedure claims, the costs for the non-CPT 69930 procedure as well as any packaged costs associated with that procedure were eliminated. What remains are only the costs associated with CPT 69930. Claims could include HCPCS codes with status indicators "A," "C," "E," "G," "H," or "N," as long as there was now only a single primary procedure within a single APC.

The extraction of "pseudo" single claims from the multiple procedure claims produced an additional 270 usable claims for a combined dataset containing 550 claims. The final step was eliminating line items from the 550 claims that were not in packaged revenue centers or did not contain either the device, the procedure, or packaged HCPCs (status indicator of "N").

Figure 1 depicts the methodology employed to create the final APC working dataset.

Figure 1:
Methodology Used to Create APC Working Dataset



2. *Determining the CY 2004 OPPS Median APC Cost*

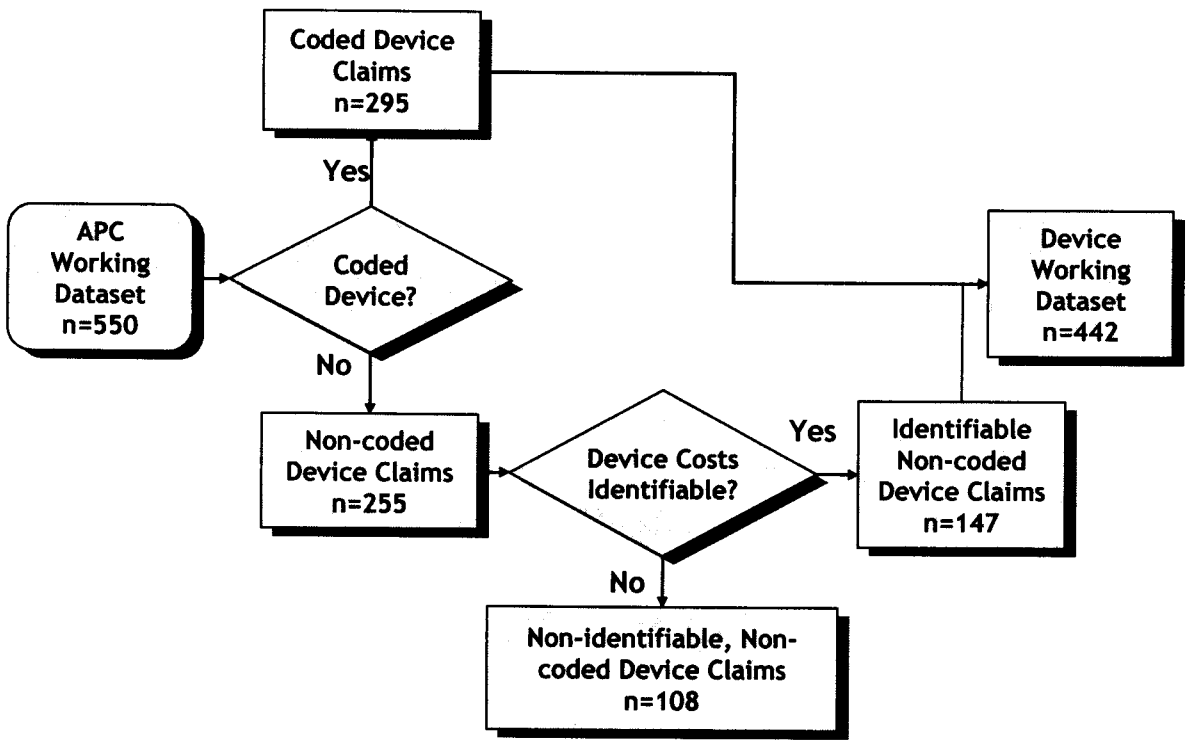
The 550 claims Lewin extracted for the APC working dataset had to include the CPT code for the cochlear implantation procedure (69930). Using this APC working dataset, we computed the APC costs for each claim. These APC costs were then converted into logs and the geometric mean was calculated. Outliers, claims with log costs that were more than three standard deviations from the geometric mean, were eliminated from the calculation of the median APC cost. Once outliers were excluded there were 544 claims in the dataset. (These results are very close to those reported by CMS; CMS reports using a total of 554 claims to calculate the APC median cost.) From the remaining claims, Lewin calculated the range, mean, median and standard deviation of the CY 2004 OPPS APC cost.

3. *Determining the CY 2004 OPPS Median Cochlear Implant Device/System Cost*

Our second objective was to determine the median cost of the device from the OPPS claims. To calculate the median device cost, only claims with identifiable device costs were used. (*Figure 2*)

The claims we kept had to include both the CPT code for the cochlear implant procedure (69930) and a device cost which could appear in revenue centers 0270, 0272, 0274 or 0278 and was or was not additionally coded L8614. Specific device costs were identified either through their HCPCS code or through revenue center designation and were used to determine the total device cost for each claim. The device working dataset included 442 claims. To calculate the median device cost, outliers were excluded based on the geometric mean and three standard deviations – this left 431 claims. Lewin then calculated the mean and median cost for the cochlear implant device/system for CY 2004.

Figure 2:
Methodology Used to Create Device Working Dataset



4. *Determining the CY 2004 Weighted Average Selling Price*

Next, Lewin calculated an actual weighted average selling price (device list price net of discounts) using confidential data supplied by the three manufacturers – Advanced Bionics, Cochlear Americas, and Med El Corporation.

5. *Calculating the CY 2004 Median APC Cost Using the Weighted Average Selling Price*

Using the results of step four above, Lewin substituted the weighted average selling price for the device cost in each claim in the device working dataset. Using the weighted average selling price, Lewin recalculated the CY 2004 median APC cost.

6. *Calculating a "New" APC Payment using a "New" Relative Weight and the CY 2006 Conversion Factor*

The final step in the Lewin analysis was to derive a "new" budget neutral CY 2006 APC payment rate. The new payment rate was derived by calculating a new relative weight and applying the CY 2006 conversion factor. To determine the new APC relative weight, Lewin first divided the APC cost calculated using the average selling price by the APC cost calculated from CY 2004 OPPS claims for each claim. This provided a ratio of these two costs for each claim. The median ratio across all claims was then identified and used to calculate a new relative weight. The "new" relative weight was then multiplied by the CY 2006 conversion factor to determine the "new" CY 2006 APC payment rate.

IV. RESULTS

Tables 1 - 4 below summarize the results of our analyses of the CY 2004 OPPS claims for the cochlear implant device/system.

A. Primary Results

In our analysis, we found the CY 2004 OPPS median APC cost to be $21,046, with a mean of $25,706 and a standard deviation of $20,760.[1] For the implant device, we found a median device cost of $16,408 in CY 2004, with a mean device cost of $20,684. See *Table 1*.

Table 1:
Results of the Lewin Group Analysis of CY 2004 OPPS Claims

	APC Cost *N = 544*	Device Cost *N = 442*
range	$1,563 - $152,934	$1,839 - $138,506
mean	$ 25,706	$ 20,684
median	**$ 21,046**	**$ 16,408**
standard deviation	$ 20,760	$ 17,087

Tables 2 and *3* contain the weighted average selling price as well as the results of the Lewin analysis using the weighted average selling price of the device. The weighted average selling price for the device is $21,827 and when this selling price is substituted for the device cost listed in the OPPS claims, the new median APC cost is $25,743.

Table 2:
Weighted Average Selling Price

Weighted Average Selling Price	$ 21,827

Table 3:
Lewin Group Analysis Using Weighted Average Selling Price

	APC Cost *N = 431*
range	$22,692 - $51,913
mean	$ 27,393
median	**$ 25,743**
standard deviation	$ 6,054

1 Lewin Group analysis of CY 2004 OPPS claims

To compute the "new" Lewin payment rate, first the ratio of the average selling price-based APC cost and the OPPS APC cost was calculated for each claim. The median of these cost ratios is 1.25 (***Table 4***). Also, shown in ***Table 4*** is the CMS proposed relative weight and the "new" Lewin APC relative weight.

Table 4:
Data Used to Calculate the "New" Lewin APC Payment Rate

Median of Claims Cost Ratios Avg Selling Price APC Cost/OPPS APC (a)	2006 Proposed Relative Weight (b)	"New" Lewin Relative Weight (c) = (a) * (b)
1.250825	366.3317	458.2168487

To determine the "new" Lewin-derived APC payment found in ***Table 5*** below, the "new" Lewin APC relative weight is multiplied by the CMS 2006 conversion factor of 59.343. The "new" Lewin APC payment rate is $27,192.

Table 5:
CMS Proposed CY 2006 APC Payment Rate vs. "New" Lewin APC Payment Rate

	Proposed CY 2006 Payment Rate	"New" Lewin CY 2005 Payment Rate
2006 APC Payment Amount	$ 21,739	$ 27,192

B. Other Results

In addition to performing the analyses described above, The Lewin Group used the dataset of 544 claims to identify the following data inconsistencies:

- The median CY 2004 OPPS APC cost for claims with a coded device differed from claims without a coded device. For claims with the code L8614 affixed, the median APC cost for the claims was $21,460 while the median APC cost for claims without a coded device was $19,622 (a difference of $1,838). The means for these two categories of claims exhibit a greater discrepancy, $28,108 for claims with a coded device and $23,051 for claims without a coded device - a difference of $5,057.

- For claims in which the device was coded (N=295) the median device cost was found to be $16,408 when outliers were excluded. This is different than the median device cost calculated from claims that did not have the device itself coded. For claims which did not have coded devices, we identified device costs on 147 claims. All of these claims had non-coded device costs/charges linked to revenue center 0278. These 147 claims were then used to calculate the median device cost for non-coded devices. The result was a median device cost of $15,302—a difference of $1,106 ($16,408 vs. $15,302).

- One provider submitted thirteen claims in which device L8614 costs were assigned to revenue center 0272 (medical/surgical supplies-sterile supply). Other providers submitted a total of four claims in which device L8614 costs were assigned to this revenue center.

Additionally, there were a total of 43 claims with the device coded that were assigned to revenue center 0274. A total of 60 claims with the device coded were assigned to the incorrect revenue center. (*Appendix A*)

- Providers also coded the procedure incorrectly. One provider submitted six claims for CPT 69930 in which the costs/charges were assigned to revenue center 0490 (ambulatory surgical care - general). A total of 19 claims were assigned to revenue center 0490. A different provider submitted five claims on which CPT 69930 was listed, but linked to revenue center 0369 (operating room services - other). In total 32 claims were submitted in which the procedure was linked to an incorrect revenue center. (*Appendix A*)

- One possible result of educational efforts concerning proper coding was that all providers who actually listed the device on the claim also properly coded the procedure with 69930. (*Appendix B*)

- In addition to analyzing the CY 2004 OPPS claims, we also built two tables which compare costs for CY 2004 OPPS claims to costs for CY 2003. One chart presents costs by CPT and the other displays costs by revenue center. One remarkable difference is the change in median cost, before removal of outliers, for L8614 from CY2003 to CY2004 from $22,339 in 2003 to $17,135 in 2004. (*Appendix C*) [Note that with outliers removed, the median device cost was $16,408.]

- Also notable is that in nearly all instances, the median for revenue centers associated with cochlear implants have declined. (*Appendix C*)

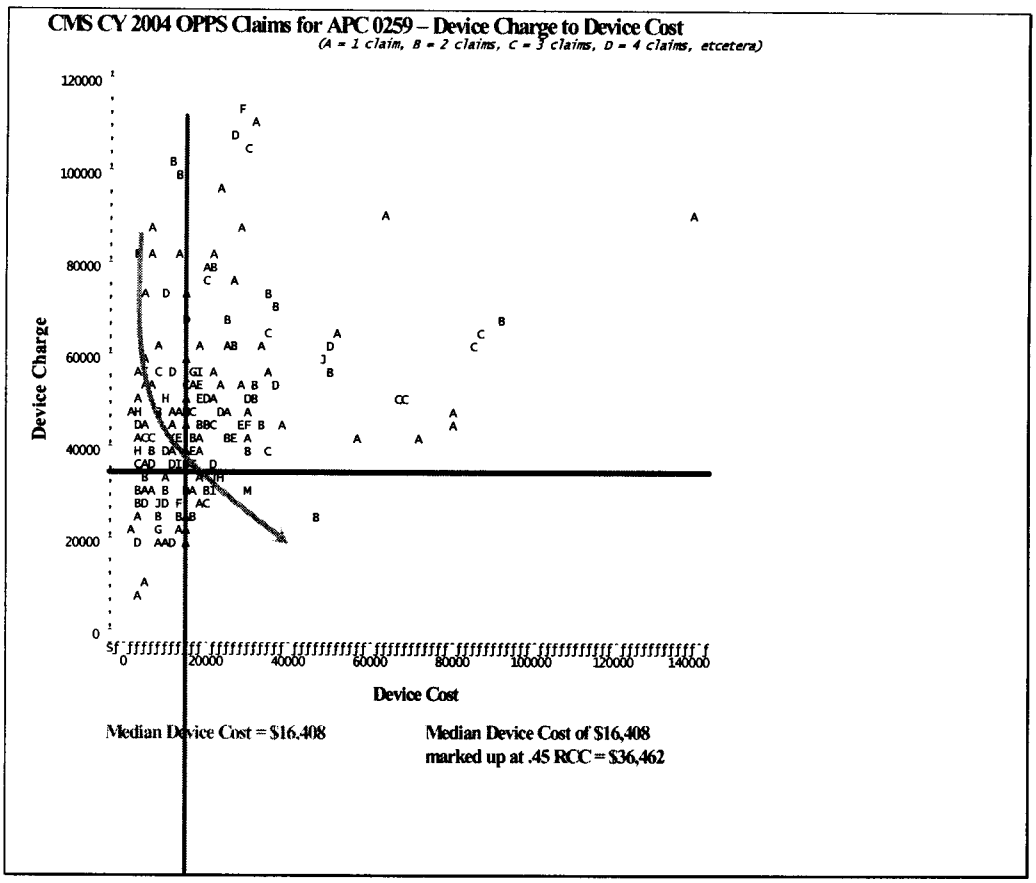
Analysis of Charges vs. Costs

In an attempt to understand the relationship between the charges and costs on the claims, we examined each of approximately 20 percent of the individual claims. We found numerous instances in which charges and costs diverged significantly (e.g., claims with charges of nearly $28,000 and costs of approximately $7,000). We also found numerous claims in which the cost was significantly higher than the charge (e.g., costs of $80,000 and charges of approximately $67,000).

We calculated the ratio of cost to charges (RCC) for each claim. We found that the RCC ranged from 0.043 to 1.769, with a mean RCC of 0.445. Because each revenue center has its own RCC, assignment of the device to the appropriate revenue center is critically important. (As noted in the section above, 60 claims had the device in the wrong revenue center.)

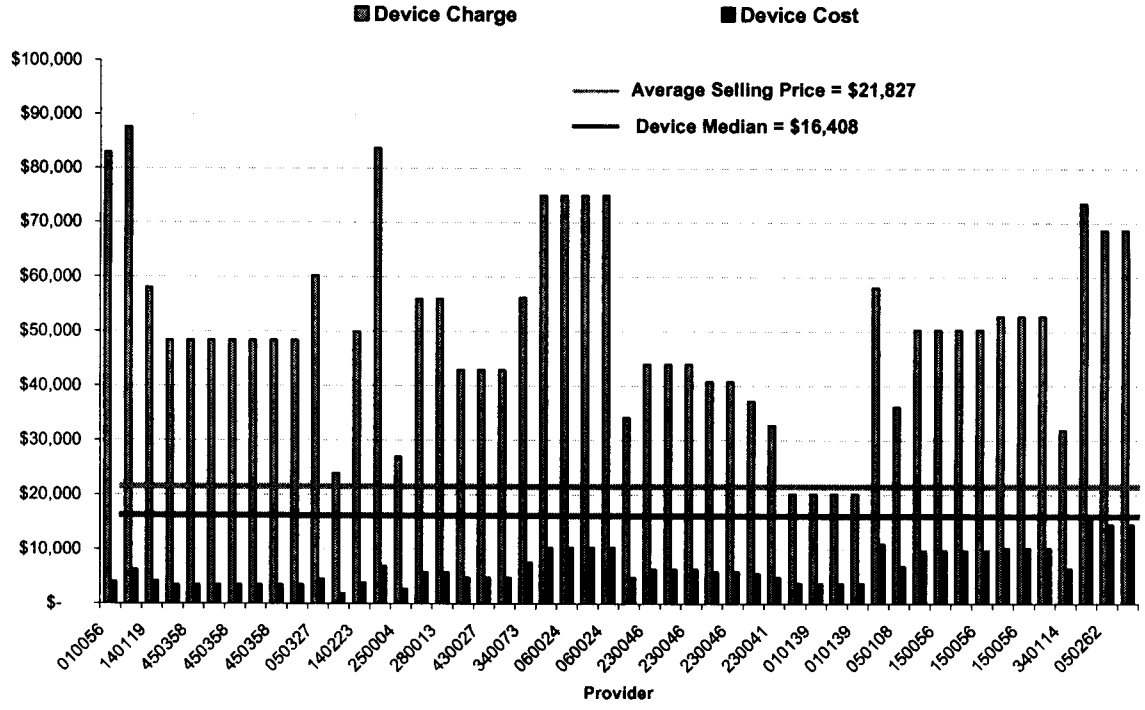
We then multiplied the CMS median cost of $16,408 by the mean RCC, obtaining a corresponding charge of $36,462. We plotted the charges vs. costs to create a picture of the distribution. (These are contained in Figure 3 below.) The large number of claims in which the device cost is low relative to a high charge for the device (claims to the left of the red line indicating the median device cost) indicates a low RCC.

Figure 3: Charges vs. Costs

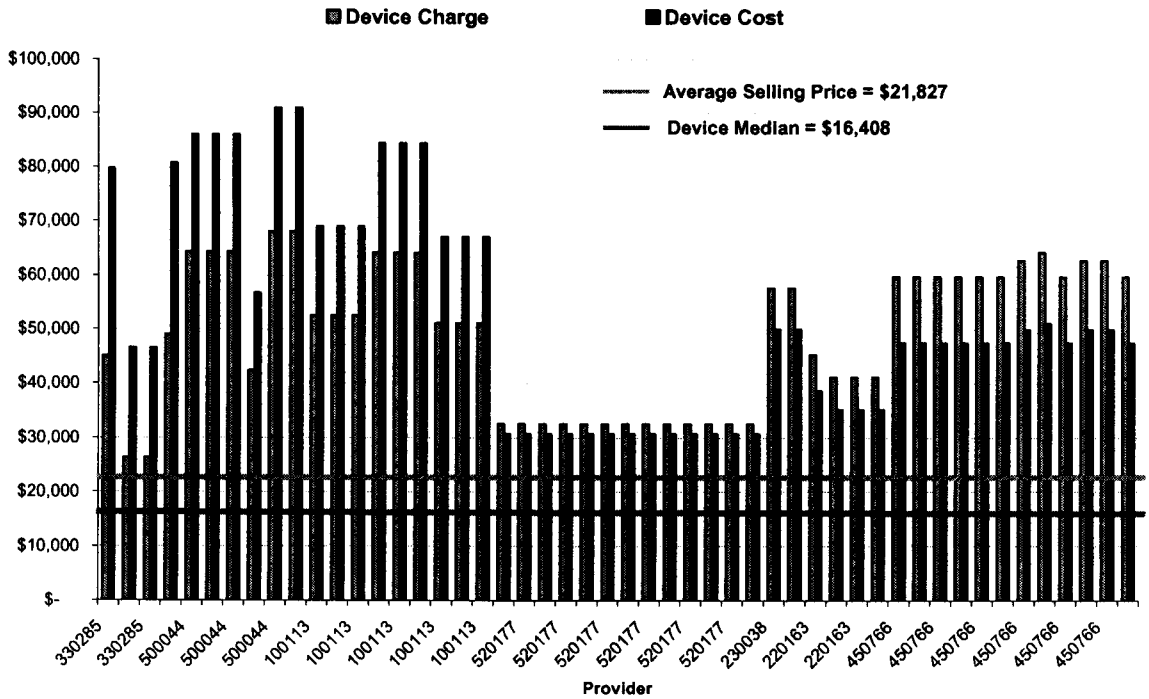


We then plotted the 50 claims with the widest divergence between charges and costs (lowest RCC) as well as the 50 claims with the highest RCC. These distributions are below, and show the extreme variance that these data contain, precluding their being used as the sole source of data for determining the cost of the device. A median cost from these data will not be reflective of the actual cost to hospitals of this device.

CMS CY 2004 OPPS Claims for APC 0259 with Device L8614 - Extreme Lows for RCC



CMS CY 2004 OPPS Claims for APC 0259 with Device L8613 - Extreme Highs for RCC



C. Discussion

The 2002 and 2004 Lewin analyses identified that the proposed CY 2003 APC and proposed CY 2005 APC payment rates were not set high enough to cover the cost of the cochlear implant device alone. This was thought to be largely due to provider coding errors which were attributed to the newness of the OPPS system and changes in pass-through payment methodology. Now that the OPPS system has been in place for several years, it was hypothesized that CMS' calculated payment rates would more accurately reflect hospital APC costs because a greater number of the claims would be correctly coded.

While hospital coding has improved, this year's study demonstrates that the proposed APC payment does not cover the cost of the device, leaving no funds for the hospital to cover facility service costs related to the procedure. The proposed APC payment rate, $21,739, is $88 less than the weighted average selling price (manufacturer's price net of discounts) of $21,827 for the device. Had the median device cost reflected the weighted average selling price of $21,827 the CY 2006 APC payment of would have provided funds to cover the cost of other hospital services associated with the procedure. The "new" Lewin derived OPPS APC 0259 payment rate of $27,192 would more accurately reflect the cost of the device and would maintain the implicit facility cost of the procedure of $5,365 ($27,192 - $21,827).

In the final CY 2005 OPPS regulation, CMS set the APC rate for 0259 at $25,307. The weighted average selling price for the cochlear device was $22,350, which comprised a more economically viable situation in that the APC payment covered some portion of the hospital facility costs as well as the cost of the device.

The proposed CY 2006 payment being **less** than the average selling price of the device is untenable for both the hospitals and the manufacturers. This payment level jeopardizes access to the cochlear implant device by Medicare beneficiaries, disadvantaging all of those Medicare beneficiaries who could benefit from implantation.

Lewin has calculated a budget neutral 2006 APC rate of $27,192, which is an eight percent increase over last year's final payment of $25,307. At this level, the payment would cover the cost of the device ($21,827) and leave roughly $5,000 to cover hospital facility costs associated with implantation of a cochlear device.

APPENDIX A

Providers Who Assigned Device L8614 to an Incorrect Revenue Center - CY2004 Claims

Medicare Provider #	Hospital Name	State	# of Claims	Revenue Center	Revenue Center Description	Total Claims by Revenue Center
340053	PRESBYTERIAN HOSPITAL	NC	3	0272	Medical/surgical supply - sterile supply	17
450193	ST LUKES EPISCOPAL HOSPITAL	TX	1			
520177	FROEDTERT MEMORIAL LUTHERAN HOSPITAL	WI	13			
010139	BROOKWOOD MEDICAL CENTER	AL	2	0274	Medical/surgical supply - prosthetic/orthotic devices	43
050224	HOAG MEMORIAL HOSPITAL PRESBYTERIAN	CA	1			
110010	EMORY UNIVERSITY HOSPITAL	GA	1			
120001	QUEENS MEDICAL CENTER	HI	1			
260022	NORTHEAST REGIONAL MEDICAL CENTER	MO	1			
260065	ST JOHNS REGIONAL HEALTH CENTER	MO	1			
260141	UNIVERSITY OF MISSOURI HOSPITAL & CLINICS	MO	1			
300003	MARY HITCHCOCK MEMORIAL HOSPITAL	NH	1			
330247	MANHATTAN EYE EAR THROAT HOSPITAL	NY	1			
330285	STRONG MEMORIAL HOSPITAL	NY	2			
360137	UNIVERSITY HOSPITALS OF CLEVELAND	OH	6			
380009	OHSU HOSPITAL	OR	5			
470003	FLETCHER ALLEN HOSPITAL OF VERMONT	VT	3			
500005	VIRGINIA MASON MEDICAL CENTER	WA	8			
500027	SWEDISH MEDICAL CENTER	WA	1			
500044	DEACONESS MEDICAL CENTER	WA	5			
510007	ST MARY'S MEDICAL CENTER	WV	3			
Total Number of Claims with Device L8614 Listed in an Incorrect Revenue Center						**60**

Providers Who Assigned Procedure 69930 to an Incorrect Revenue Center – CY2004

Medicare Provider #	Hospital Name	State	# of Claims	Revenue Center	Revenue Center Description	Total Claims by Revenue Center
060034	SWEDISH MEDICAL CTR	CO	2	0361	Operating room services - minor surgery	8
330078	CATHOLIC HEALTH SYSTEM AT SISTERS OF CHARITY	NY	1			
330189	ALBANY MEDICAL CENTER/SOUTH CLINICAL CAMPUS	NY	5			
310051	OVERLOOK HOSPITAL	NJ	3	0369	Operating room services - other	3
040114	BAPTIST HEALTH MEDICAL CENTER-LITTLE ROCK	AR	1	0490	Ambulatory surgical care - general	19
070036	JOHN DEMPSEY HOSPITAL	CT	4			
240080	FAIRVIEW UNIVERSITY MEDICAL CENTER	MN	6			
280013	NEBRASKA MEDICAL CENTER, THE	NE	2			
310001	HACKENSACK UNIVERSITY MEDICAL CENTER	NJ	1			
310119	UMDNJ UNIVERSITY HOSPITAL	NJ	2			
430027	SIOUX VALLEY HOSPITAL UNIVERSITY MEDICAL CENTER	SD	3			
490032	VIRGINIA COMMONWEALTH UNIVERSITY HEALTH SYSTEM	VA	1	0510	Clinical - general classification	1
040016	UAMS MEDICAL CENTER	AR	1	0710	Recovery room - general classification	1
Total Number of Claims with Procedure 69930 Listed in an Incorrect Revenue Center						**32**

APPENDIX B

Providers Who Listed Device L8614, But Listed A Procedure Other Than 69930 – CY2004

Medicare Provider #	Hospital Name	State	# of Claims	CPT	Procedure Description	Total Claims by CPT
	For all claims with Device L8614, CPT 69930 also appears on the claim					295

APPENDIX C

Costs by CPT/HCPCS Code: CY 2004 & CY 2003

(Note: Outliers have not been excluded)

CPT/ HCPCS	2004 Cochlear Claims							2003 Cochlear Claims						
	Freq	% of Claims (N=544)	Min	Max	Mean	Median	Standard Deviation	Freq	% of Claims (N=499)	Min	Max	Mean	Median	Standard Deviation
00120	4	0.7%	62.35	215.45	173.92	208.93	74.63	-	0.0%	-	-	-	-	-
69930	555	102.0%	-	10,411.48	2,242.63	1,955.06	1,231.46	507	101.6%	240.92	20,583.47	2,265.05	1,988.60	1,517.28
93012	1	0.2%	64.86	64.86	64.86	64.86	-							
94760	9	1.7%	8.63	53.07	21.05	17.66	13.82	3	0.6%	13.12	28.93	23.66	28.93	9.13
94761	8	1.5%	9.44	84.25	33.54	19.19	31.00	4	0.8%	29.84	106.65	60.34	52.44	37.46
99141	2	0.4%	45.35	267.66	156.50	156.50	157.19							
99218	38	7.0%	13.54	347.22	130.94	96.63	93.22	41	8.2%	20.16	863.61	134.12	66.28	146.96
99219	5	0.9%	193.18	1,070.30	471.31	306.14	351.97	2	0.4%	113.78	113.78	113.78	113.78	-
C1713	11	2.0%	45.22	31,399.52	5,274.33	218.28	11,281.09							
C1729	3	0.6%	4.51	5.42	5.12	5.42	0.52	-	0.0%	-	-	-	-	-
C1760	4	0.7%	13.13	131.29	45.17	18.12	57.61							
C1763	1	0.2%	32.29	32.29	32.29	32.29	-							
C1781	9	1.7%	31.39	279.11	68.27	46.81	79.38	-	0.0%	-	-	-	-	-
G0264	1	0.2%	21.27	21.27	21.27	21.27	-	1	0.2%	267.64	267.64	267.64	267.64	-
J0170	37	6.8%	0.64	18.75	5.34	2.85	5.65	27	5.4%	0.74	15.21	6.32	1.68	5.77
J0290	1	0.2%	4.15	4.15	4.15	4.15	-	-	0.0%	-	-	-	-	-
J0295	4	0.7%	6.03	23.45	13.95	13.15	8.02	1	0.2%	16.57	16.57	16.57	16.57	-
J0330	27	5.0%	1.83	15.37	6.53	6.30	3.37	21	4.2%	0.64	8.24	3.61	3.85	1.66
J0360	1	0.2%	5.39	5.39	5.39	5.39	-	3	0.6%	6.59	15.89	10.64	9.44	4.76
J0460	3	0.6%	1.56	10.45	4.95	2.85	4.80	1	0.2%	3.76	3.76	3.76	3.76	-
J0630	11	2.0%	4.16	8.34	4.54	4.16	1.26	16	3.2%	3.60	16.96	6.13	4.24	4.46
J0690	93	17.1%	0.64	52.35	9.82	6.20	10.10	80	16.0%	1.09	156.49	13.42	6.53	21.10
J0694	1	0.2%	3.53	3.53	3.53	3.53	-							
J0696	12	2.2%	41.23	97.31	56.93	41.23	23.92	11	2.2%	4.15	85.03	48.68	42.51	21.55
J0697	7	1.3%	10.03	39.61	16.43	10.92	10.86	2	0.4%	18.42	50.87	34.64	34.64	22.95

(Note: Outliers have not been excluded)

CPT/ HCPCS	2004 Cochlear Claims							2003 Cochlear Claims						
	Freq	% of Claims (N=544)	Min	Max	Mean	Median	Standard Deviation	Freq	% of Claims (N=499)	Min	Max	Mean	Median	Standard Deviation
J0744	1	0.2%	48.65	48.65	48.65	48.65	-							
J0780	1	0.2%	2.83	2.83	2.83	2.83	-							
J1094	6	1.1%	1.88	13.09	5.87	6.07	4.10	1	0.2%	10.28	10.28	10.28	10.28	-
J1100	54	9.9%	0.40	20.95	6.24	5.70	3.90	25	5.0%	1.63	16.07	5.95	5.79	3.65
J1160	1	0.2%	5.34	5.34	5.34	5.34	-							
J1170	6	1.1%	1.04	10.19	5.64	5.69	4.24	6	1.2%	1.52	4.71	3.40	4.04	1.28
J1200	5	0.9%	1.00	13.16	4.47	2.96	4.95	4	0.8%	0.94	1.86	1.47	1.54	0.41
J1260	50	9.2%	9.01	74.95	22.72	18.34	12.03	57	11.4%	2.88	94.29	25.04	21.47	14.18
J1580	1	0.2%	1.13	1.13	1.13	1.13	-	1	0.2%	0.97	0.97	0.97	0.97	-
J1590	1	0.2%	37.60	37.60	37.60	37.60	-							
J1644	3	0.6%	2.85	19.92	9.62	6.10	9.06							
J1720	3	0.6%	1.78	6.10	3.60	2.91	2.24	1	0.2%	13.53	13.53	13.53	13.53	-
J1790	8	1.5%	5.02	18.02	10.18	9.88	3.58	4	0.8%	2.59	10.44	5.81	5.10	3.42
J1815	3	0.6%	0.31	2.79	1.31	0.83	1.31							
J1885	11	2.0%	1.61	8.87	5.57	5.12	1.79	5	1.0%	4.71	13.02	9.62	9.41	3.49
J1940	3	0.6%	2.85	4.65	3.45	2.85	1.04	-	0.0%	-	-	-	-	-
J1956	2	0.4%	36.85	86.79	61.82	61.82	35.31	2	0.4%	22.13	57.68	39.90	39.90	25.14
J2000	2	0.4%	2.29	4.66	3.48	3.48	1.68	29	5.8%	1.63	62.89	6.85	4.06	11.14
J2175	16	2.9%	0.80	11.14	6.06	5.57	2.84	17	3.4%	1.68	13.77	4.91	4.11	2.81
J2180	1	0.2%	0.52	0.52	0.52	0.52	-	1	0.2%	2.21	2.21	2.21	2.21	-
J2250	80	14.7%	0.65	17.88	5.16	4.11	3.25	53	10.6%	0.66	17.14	4.08	3.85	3.15
J2270	48	8.8%	0.75	66.74	9.27	5.65	10.92	61	12.2%	0.86	33.26	5.59	3.94	5.41
J2271	2	0.4%	6.10	18.32	12.21	12.21	8.64							
J2275	13	2.4%	2.47	34.14	9.87	7.03	9.19	8	1.6%	3.33	6.96	5.04	4.89	1.20
J2370	23	4.2%	1.31	12.58	5.15	4.36	2.26	11	2.2%	0.88	7.63	4.09	3.81	1.62
J2405	189	34.7%	2.45	141.37	31.67	27.04	16.38	210	42.1%	5.29	295.22	34.64	27.08	32.27
J2550	34	6.3%	2.01	16.27	5.49	5.04	3.12	35	7.0%	1.75	19.51	5.54	4.15	4.37
J2710	21	3.9%	2.75	33.08	8.55	6.95	6.24	9	1.8%	3.07	19.19	8.76	7.07	4.42
J2765	56	10.3%	0.26	16.25	5.23	2.95	4.34	59	11.8%	0.22	19.10	5.72	5.13	3.88
J2912	17	3.1%	2.01	36.78	16.40	11.15	11.29							
J3010	235	43.2%	0.47	45.52	9.79	8.08	7.88	270	54.1%	0.31	56.09	9.54	7.08	8.05
J3360	1	0.2%	5.08	5.08	5.08	5.08	-	2	0.4%	2.58	7.10	4.84	4.84	3.20
J3370	1	0.2%	14.08	14.08	14.08	14.08	-	1	0.2%	22.57	22.57	22.57	22.57	-

(Note: Outliers have not been excluded)

CPT/ HCPCS	2004 Cochlear Claims							2003 Cochlear Claims						
	Freq	% of Claims (N=544)	Min	Max	Mean	Median	Standard Deviation	Freq	% of Claims (N=499)	Min	Max	Mean	Median	Standard Deviation
J3480	9	1.7%	5.70	20.03	16.79	19.02	5.25	3	0.6%	5.18	24.43	18.01	24.43	11.11
J3490	11	2.0%	2.51	153.80	35.61	6.40	55.84	3	0.6%	4.85	9.62	6.44	4.86	2.75
J7030	5	0.9%	0.99	19.71	9.23	11.15	7.45	-	0.0%	-	-	-	-	-
J7040	5	0.9%	9.48	111.45	39.74	32.24	41.45							
J7050	2	0.4%	18.66	21.45	20.05	20.05	1.97	-	0.0%	-	-	-	-	-
J7051	1	0.2%	0.60	0.60	0.60	0.60	-							
J7060	1	0.2%	5.18	5.18	5.18	5.18	-							
J7120	26	4.8%	1.22	63.97	16.67	12.44	15.44	12	2.4%	1.28	54.63	13.46	7.07	14.60
J7500	1	0.2%	1.74	1.74	1.74	1.74	-							
L8613	1	0.2%	1,482.70	1,482.70	1,482.70	1,482.70	-	2	0.4%	168.70	386.13	277.42	277.42	153.75
L8614	295	54.2%	1,750.81	67,265.95	22,595.74	17,135.98	17,757.66	263	52.7%	2,638.34	81,636.86	24,412.71	22,339.08	14,193.60
L8699	1	0.2%	8,964.02	8,964.02	8,964.02	8,964.02	-	2	0.4%	358.87	408.63	383.75	383.75	35.19
Q0081	1	0.2%	42.95	42.95	42.95	42.95	-							
Q0179	3	0.6%	28.03	28.03	28.03	28.03	-							

Legend of Highlighted CPT/HCPCS Codes:

69930	Implant cochlear device
99218	Observation care
J0170	Adrenalin epinephrin inject
J0690	Cefazolin sodium injection
J2250	Inj midazolam hydrochloride
J2270	Morphine sulfate injection
J2405	Ondansetron HCL injection, per 1 mg
J2765	Metoclopramide HCL injection up to 10 mg
J3010	Fentanyl citrate injeciton
L8614	Cochlear device/system

Costs by Revenue Center: CY 2004 & CY 2003

(Note: Outliers have not been excluded)

Revenue Center	2004 Cochlear Claims							2003 Cochlear Claims						
	Freq	% of Claims (N=544)	Min	Max	Mean	Median	Standard Deviation	Freq	% of Claims (N=499)	Min	Max	Mean	Median	Standard Deviation
0250	698	128.3%	$ 0.09	$ 543.87	$ 99.94	$ 73.02	$ 96.35	595	119.2%	$ 0.10	$ 693.51	$ 118.76	$ 80.66	$ 122.85
0251	91	16.7%	2.85	269.10	24.32	8.95	41.53	87	17.4%	0.88	192.75	34.24	$ 12.95	41.42
0252	65	11.9%	2.35	184.00	28.38	11.23	32.62	46	9.2%	2.02	329.15	29.96	$ 16.12	51.18
0254	3	0.6%	6.55	6.95	6.68	6.55	0.23							
0258	294	54.0%	0.83	294.04	45.30	31.81	43.10	264	52.9%	0.69	286.87	48.25	$ 39.83	41.05
0259	101	18.6%	0.51	277.45	38.94	13.93	52.04	91	18.2%	0.02	272.50	36.90	$ 12.54	51.33
0260	1	0.2%	42.95	42.95	42.95	42.95	-							
0270	384	70.6%	0.38	34,915.37	1,874.29	292.48	5,265.73	353	70.7%	1.73	37,000.56	1,841.20	$ 340.05	5,080.58
0271	118	21.7%	0.87	662.73	54.14	33.58	90.98	91	18.2%	0.80	7,315.55	166.55	$ 35.43	768.07
0272	394	72.4%	0.55	69,124.03	2,361.17	448.05	7,342.97	325	65.1%	0.74	48,454.21	2,910.49	$ 665.48	7,790.20
0274	43	7.9%	3,951.13	86,287.50	24,815.79	18,163.23	22,060.96	86	17.2%	27.52	76,705.05	26,602.43	$ 26,132.03	15,092.31
0278	516	94.9%	0.79	134,974.10	18,132.23	14,457.28	19,717.20	429	86.0%	6.43	155,837.72	17,386.23	$ 14,665.23	16,611.98
0279	18	3.3%	0.53	34,238.05	5,495.76	72.04	11,600.28	23	4.6%	0.39	19,901.29	1,464.13	$ 173.49	4,219.67
0360	523	96.1%	-	10,411.48	2,282.36	1,978.21	1,243.23	459	92.0%	242.87	11,588.47	2,259.20	$ 2,034.63	1,186.26
0361	8	1.5%	38.32	2,737.25	1,029.97	407.62	1,038.02	18	3.6%	16.72	20,583.47	4,007.19	$ 2,481.87	5,007.59
0369	3	0.6%	945.57	1,827.82	1,533.73	1,827.82	509.36	8	1.6%	1,214.01	2,612.00	1,653.53	$ 1,335.02	558.74
0370	491	90.3%	16.76	835.23	261.67	211.65	170.05	437	87.6%	8.31	1,358.44	272.62	$ 211.83	183.93
0372	1	0.2%	45.35	45.35	45.35	45.35	-	1	0.2%	82.50	82.50	82.50	$ 82.50	
0379	4	0.7%	57.75	96.77	77.44	77.62	19.65	6	1.2%	10.61	69.33	38.85	$ 43.59	24.40
0460	17	3.1%	8.63	84.25	26.93	17.66	23.61	8	1.6%	13.12	74.91	44.39	$ 29.90	25.76

(Note: Outliers have not been excluded)

Revenue Center	2004 Cochlear Claims							2003 Cochlear Claims						
	Freq	% of Claims (N=499)	Min	Max	Mean	Median	Standard Deviation	Freq	% of Claims (N=499)	Min	Max	Mean	Median	Standard Deviation
0490	19	3.5%	$ 919.76	$ 2,604.04	$ 1,930.97	$ 2,055.52	$ 483.84	25	5.0%	$ 240.92	$ 3,180.38	$ 1,065.89	$ 962.29	$ 687.02
0510	1	0.2%	224.75	224.75	224.75	224.75								
0636	930	171.0%	0.26	153.80	13.81	8.97	16.39	920	184.4%	0.22	295.22	15.34	$ 8.68	21.39
0710	509	93.6%	39.39	1,950.06	347.18	281.60	235.85	477	95.6%	26.33	1,731.99	348.87	$ 307.88	222.84
0719	16	2.9%	83.65	549.39	287.49	277.17	121.79	21	4.2%	57.03	400.45	226.53	$ 263.49	92.81
0732	1	0.2%	64.86	64.86	64.86	64.86								
0760	12	2.2%	74.76	132.99	103.87	99.12	16.65	9	1.8%	63.00	196.91	101.51	$ 78.76	43.04
0762	89	16.4%	13.54	1,070.30	241.33	161.82	222.89	105	21.0%	6.65	863.61	192.02	$ 131.06	169.84

Legend of Revenue Center Codes

0250	Pharmacy-general
0251	Pharmacy-generic drugs
0252	Pharmacy-nongeneric drugs
0254	Pharmacy-incidental
0258	Pharmacy-IV solutions
0259	Pharmacy-other pharmacy
0260	IV therapy-general
0270	Medical/surgical supplies-general
0271	Medical/surgical supplies-nonsterile supply
0272	Medical/surgical supplies-sterile supply
0274	Medical/surgical supplies prosthetic/orthotic devices
0278	Medical/surgical supplies-other implants
0279	Medical/surgical supplies-other devices
0360	Operating room services-general classification
0361	Operating room services-minor surgery
0369	Operating room services-other operating room services
0370	Anesthesia-general
0372	Anesthesia-incident to other diagnostic service
0379	Anesthesia-other
0460	Pulmonary function-general
0490	Ambulatory surgical care-general
0510	Clinical-general
0636	Drugs requiring specific identification-detailed coding
0710	Recovery room-general
0719	Recovery room-other
0732	EKG/ECG-telemetry
0760	Treatment or observation room-general
0762	Treatment or observation room-observation room

APPENDIX D

Most Commonly Found Disallowed CPT/HCPCS Codes - CY2004

CPT/HCPCS Code	Procedure Description	# of Claims on which CPT appears
95920	Intraoperative neurophysiology testing, per hour	163
90784	Therapuetic, prophylactic or diagnostic injection; intravenous	57
92584	Electrochochleography	51
99218	Initial observation care, per day, for the evaluation and management of a patient which requires these three key components: a detailed or comprehensive history; a detailed or comprehensive examination; and medical decision making that is straightforward or of low complexity	49
Q0081	Infusion therapy, using other than chemotherapeutic drugs, per visit	34
99201	Office or other outpatient visit	28
95927	Short-latency somatosensory evoked potential study, stimulation or any/all peripheral nerves or skin sites, recording from the central nervous system, in trunk or head	26
92516	Facial nerve function studies	19
94640	Pressurized or non-pressurized inhalation treatment for acute airway obstruction of for sputum induction for diagnostic purposes	16
94664	Demonstration and / or evaluation of patient utilization of an aerosol generator, nebulizer, metered dose inhaler or IPPB device	14

(Source: Multiple Procedure Claims)

Disallowed CPT/HCPCS Codes by Medicare Provider Number

Medicare Provider #	Hospital Name	State	CPT	# of Claims on which CPT appears
030103	MAYO CLINIC HOSPITAL	AZ	86920	1
			86927	1
			93325	1
			99219	2
050324	SCRIPPS MEMORIAL HOSPITAL LA JOLLA	CA	20926	1
060014	PRESBYTERIAN/ST LUKE'S MEDICAL CTR	CO	69631	1
060022			76000	1
			94761	1
060024	UNIVERSITY OF COLORADO HOSP AUTHORITY	CO	94760	1
070022	YALE-NEW HAVEN HOSPITAL	CT	69667	5
100022	JACKSON HEALTH SYSTEM	FL	15770	2
			20922	1
			69620	1
100128	TAMPA GENERAL HOSPITAL	FL	11420	1
			64716	1
			69670	2
			78461	1
			78478	1
			93017	1
			93325	1
			94799	1
110161	NORTHSIDE HOSPITAL	GA	69799	1
130006	ST LUKES REGIONAL MEDICAL CENTER	ID	69631	1
140091	CARLE FOUNDATION HOSPITAL	IL	69620	1
150056	CLARIAN HEALTH PARTNERS, INCORPORATED	IN	11441	1
			94762	2
160058	UNIVERSITY OF IOWA HOSPITAL & CLINICS	IA	69310	1
			93732	1
170122	VIA CHRISTI REGIONAL MEDICAL CENTER	KS	99211	1
190015	NORTH OAKS MEDICAL CENTER	LA	69666	1
			69667	1
220075	MASSACHUSETTS EYE AND EAR INFIRMARY	MA	99212	2
230038	SPECTRUM HEALTH-DOWNTOWN CAMPUS	MI	69620	1
			69631	1
230046	UNIVERSITY OF MICHIGAN HOSPITAL	MI	69501	1
			94760	2
			94799	12
250001	UNIVERSITY OF MISSISSIPPI MED CENTER	MS	92603	1
250004	NORTH MISSISSIPPI MEDICAL CENTER	MS	00120	2
			94761	2
250138	RIVER OAKS HOSPITAL	MS	00120	1
			94010	3
260027	RESEARCH MEDICAL CENTER	MO	69436	1

(Source: Multiple Procedure Claims)

Medicare Provider #	Hospital Name	State	CPT	# of Claims on which CPT appears
260065	ST JOHNS REGIONAL HEALTH CENTER	MO	36600 71275 93325	1 1 1
260138	ST LUKES HOSPITAL OF KANSAS CITY	MO	90782	5
280013	NEBRASKA MEDICAL CENTER,THE	NE	11421 95868	1 4
330100	NEW YORK EYE AND EAR INFIRMARY	NY	17999	1
330169	BETH ISRAEL MEDICAL CENTER	NY	70134	1
330203	CROUSE HOSPITAL	NY	76000	6
340040	PITT COUNTY MEMORIAL HOSPITAL	NC	93325	1
340061	UNIVERSITY OF NORTH CAROLINA HOSPITAL	NC	70240	5
340113	CAROLINAS MEDICAL CENTER/BEHAV HEALTH	NC	99211	3
360051	MIAMI VALLEY HOSPITAL	OH	90782	1
360085	OHIO STATE UNIVERSITY HOSPITAL	OH	00120 69310	3 1
360180	CLEVELAND CLINIC FOUNDATION	OH	93744	1
370028	INTEGRIS BAPTIST MEDICAL CENTER	OK	15740 67900 69711	1 1 1
370091	SAINT FRANCIS HOSPITAL, INC	OK	70240	1
380009	OHSU HOSPITAL	OR	20926 69620 94761	5 1 3
390050	ALLEGHENY GENERAL HOSPITAL	PA	69450 69643	1 1
420004	MEDICAL UNIVERSITY HOSPITAL	SC	69990 86927 93017	1 1 1
440019	BAPTIST HOSPITAL OF EAST TENNESSEE	TN	90782	1
440039	VANDERBILT UNIVERSITY HOSPITAL	TN	20926	1
440082	ST THOMAS HOSPITAL	TN	69667	3
450021	BAYLOR UNIVERSITY MEDICAL CENTER	TX	31525 36430 69799 69949 76000 86927	1 1 1 1 1 1
450040		TX	94010	2
450068	MEMORIAL HERMANN HOSPITAL	TX	67912	1
450184	MEMORIAL HERMANN HEALTHCARE SYSTEM	TX	69949	1
450388	METHODIST HOSPITAL	TX	14020 64999 69310	1 1 1
490007	SENTARA NORFOLK GENL HOSP	VA	76000	1

(Source: Multiple Procedure Claims)

Medicare Provider #	Hospital Name	State	CPT	# of Claims on which CPT appears
490032	VIRGINIA COMMONWEALTH UNIVERSITY HEALTH SY	VA	69399 94760 99141 99219	1 2 1 3
490057	SENTARA VIRGINIA BEACH GENERAL HOSPITAL	VA	69424 69436	1 1
500005	VIRGINIA MASON MEDICAL CENTER	WA	21235 69641 69711 69820 69910 69990 70240 76375 94760	1 1 1 1 1 1 2 1 1
500027	SWEDISH MEDICAL CENTER	WA	20926 69720	1 3
500129	TACOMA GENERAL ALLENMORE HOSPITAL	WA	69720 94761	1 2
520177	FROEDTERT MEMORIAL LUTHERAN HOSPITAL	WI	69670	1

(Source: Multiple Procedure Claims)

Submitter : Dr. Scott Taber **Date:** 09/13/2005

Organization : Sisters of Charity Providence Hospitals

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attached

CMS-1501-P-351-Attach-1.DOC

Sisters of Charity Providence Hospitals
Wound Care Center
114 Gateway Corporate Blvd, Suite 450
Columbia, SC 29203

September 12, 2005

Mr. Herb Kuhn
Director, Center for Medicare Management
Centers for Medicare and Medicaid Services
200 Independence Ave. SW
Washington, DC 20201

Regarding: ODE CMS-1501-P Changes to the HOPPS 2006 Payment Rates

Dear Mr. Kuhn:

Our wound care center and hospital system has discovered an error in the proposed rule, CMS-1501-P, "Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates" relating to the payment rates for the products Apligraf (C1305) and Dermagraft (C9201).

It is crucial that our patients have access to these treatments in order to lower the frequency of amputations at our hospital. We respectfully request that the payment rates for Apligraf and Dermagraft be corrected in the final rule. Apligraf remains the only FDA approved treatment for both venous leg and diabetic foot ulcers.

The proposed rule both Apligraf and Dermagraft would be incorrectly paid based on rates derived from claims data in stead of payment at Average Sales Price plus eight percent. Both products are showing a tremendous decrease in payment:

> Apligraf -- 2005 outpatient rate $1,130.88; 2006 proposed outpatient rate $766.84
> Dermagraft -- 2005 outpatient rate $529.54; 2006 proposed outpatient rate $368.32

It was our understanding that in 2006 Medicare proposed to pay specified covered outpatient drugs at average sales price plus six percent for the acquisition cost of the drug. The current rule reflects a different payment structure.

We believe there may have been some confusion in the proposed rule because the products are reimbursed in the physician's office under codes with different descriptors.

Thank you very much for looking into this error as we hope to continue these valuable treatments within our hospital system.

Sincerely,

Scott W. Taber, MD

Submitter : Mrs. Sabine McCurry **Date: 09/13/2005**

Organization : Palmetto Health Richland

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

The proposed rule is intended to provide reimbursement of ASP+8% for covered products, in the case of Apligraf and Dermagraft, the reimbursement rate is proposed to be 30% below the selling price of the product.

Apligraf -- 2005 outpatient rate $1,130.88; 2006 proposed outpatient rate $766.84
Dermagraft -- 2005 outpatient rate $529.54; 2006 proposed outpatient rate $368.32

Reimbursement at this rate would jeopardize patient access to Apligraf and Dermagraft and that would have a very negative impact on quality of care.

Please ensure us in 2006 that Apligraf and Dermagraft are reimbursed as a specified covered drug, at ASP+8%.

Submitter : Dr. Brian Peters **Date:** 09/13/2005

Organization : Dallas Otolaryngology Associates

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1501-P-357-Attach-1.DOC

9/13/2005

Re: CMS-1501-P

Dear Sirs:

I am writing to express my concern over the proposed reduction in cochlear implant reimbursement for 2006. I was so excited when CMS increased its reimbursement for 2005 to $25,307, for this made it much more likely that I and the hospital where I do my surgery would be able to continue providing cochlear implant services to our Medicare patients. However if the rate is decrease at all as proposed for 2006 I am fearful that all providers and hospitals will be forced to reduce access to our Medicare patients because of a net loss that will be incurred.

This is unfortunate because of the tremendous benefits profoundly hearing impaired patients receive from cochlear implants. It can totally change their life from one of deafness to productive hearing. This treatment has been proven cost effective by several published studies and is well worth our health care dollars. I am currently seeing Medicare patients who are coming to our cochlear implant center because they were denied treatment at other facilities because of cost issues. I fear that a further reduction in reimbursement will only make this problem worse, since there are only a few facilities that provide this treatment.

It is my request that CMS use accurate external device cost data as determined by the Lewin Group study and recalculate the relative weight of APC 0259. The 2006 reimbursement should be the same as 2005 plus inflation and other update factors.

Thank you for your consideration.

Dr. Peters

Submitter : Mr. Tad Gomez **Date:** 09/13/2005

Organization : MCG Health System

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-P-358-Attach-1.DOC

MCG
Health System

September 13, 2005

Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore MD 21244-1850

To Whom It May Concern:

I am writing to express my concern and opposition to CMS's proposed to pay for outpatient drugs and biologicals at 106 percent of the manufacturer's average sales price (ASP). A June 30, 2005, report on hospital outpatient department pharmacy handling costs prepared by the Medicare Payment Advisory Commission (MedPAC) noted that these expenses were "not insignificant" and that they "made up 26 percent to 28 percent of pharmacy departments' direct costs." Instead of accepting MedPAC's analysis, CMS proposes to pay only "an additional 2 percent of the ASP scaled for budget neutrality to cover the handling costs of these drugs."

This reimbursement formula is wholly inadequate to cover handling costs of drugs. Hospitals may be forced to limit or eliminate the treatment of patients in outpatient settings. The ramifications of instituting this formula will be disastrous. The places and processes of providing services will change - to the detriment of patients who will not receive treatment by their providers of choice. Inadequate reimbursement to hospital outpatient departments will impact the quality, safety and level of their services.

Rather, I support the proposal being made by the Association of Community Cancer Centers (ACCC) that CMS consider an allowance of 8% to cover pharmacy handling and overhead expenses for all drugs reimbursed under the hospital OPPS, in addition to ASP + 6% to cover the drug acquisition cost.

Thank you for your consideration of my comments and if you should have any questions regarding this issue, please do not hesitate to contact me via email at tgomez@mcg.edu.

Respectfully submitted,

Tad A. Gomez, M.S.
Director of Pharmacy
MCG Health System

Submitter : Mr. Phil Martin **Date:** 09/13/2005

Organization : St. Cloud Hospital

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

Rural hospitals are struggling to even cover the cost of these devices yet alone the cost of performing the procedure, drugs, supplies, and the outpatient stay. The price associated with these devices does not differ from rural to urban. Attention should not be placed on payment, but on controlling device cost. We will operate at a loss if payment is decreased because technology cost will only inflate.

Submitter : **Dr. Patrick Antonelli** **Date: 09/13/2005**

Organization : **University of Florida**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Current CMS payments for cochlear implants result in a significant financial loss. This compromises our ability to offer this hearing restoration services to everyone that needs it. If funding is further decreased (14% as proposed), it will be even more difficult to offer these services. Hence, I am strongly against the proposed change. Thank you for your consideration.

Patrick

Patrick J. Antonelli, M.D.
Professor & Chair, Department of Otolaryngology
University of Florida
Chief Medical Information Officer
Shands HealthCare
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